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CDNA - CareDx Inc Cell-Free DNA Program – Updates from ISHLT

EVENT DATE/TIME: APRIL 16, 2015 / 3:30PM GMT

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PRESENTATION

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Good evening, ladies and gentlemen. Welcome to the CareDx Cell-Free DNA Program Updates from ISHLT. At this time, all participant lines are in a listen-only mode to reduce background noise. But later we will be conducting a Q&A session and instructions will follow at that time. As a reminder, this conference call is being recorded.

I would now like to turn the call over to our host for this evening's program, Peter Maag, Peter.

Peter Maag *- CareDx, Inc. - President and CEO*

Welcome. Greetings from Nice. Let me tell you that this is one of the toughest dates to spend part of your spring. If you've ever spent a week in April at the Cote d'Azur, make this part of your bucket list.

Let me turn now to our serious topic. Thank you for joining the call. Transplant patient care is one of the most complex things one can think about. Imagine, transplant clinicians filled with patients that live with foreign organs in their body. At CareDx we help our transplant clinicians manage these complex cases.

These patients, after having experienced significant cardiovascular events, are at a constant risk of rejection, site of infection, face real impairment, and many experience a diagnosis of cancer. Transplant patients are one of the most complex and high cost patients in the healthcare system. They are at the top of the pyramid. And they are also on the top of the pyramid in respect to medical science. Imagine managing these complex patients.

And let me be a bit provocative here. Today, transplant clinicians make NEAT decisions. NEAT stands for non-rational, empirical, acute decision-making. At CareDX, we have the vision to help doctors make RAPID decisions. And RAPID decision stands for rational, personalized, immediate decision-making.

With AlloMap, our first product, we support heart transplant patient surveillance and help clinicians to identify those patients that are at a low risk of rejection. We have exciting new data that indicates that the AlloMap variability can be interpreted in the context of long term outcome. The cell-free DNA, CareDx is a pioneer in bringing sequencing solutions to the clinic, here for the field of transplantation.

Last year, at the IPO road show, we have promised to use our existing sample database and profile cell-free DNA in the field of transplantation. This year, we deliver. With CARGO II, we are breaking new grounds against current standards.

Today, we bring two colleagues with us. With John Sninsky, we have attracted to CareDX a topnotch scientist that will help us in the discovery and development of these solutions. And with Jim Yee, we have a renowned world expert in the field of transplant clinical development at CareDx.

Now ladies and gentlemen, let me hand it over to John Sninsky.

John Sninsky - *CareDx, Inc. - Chief Scientific Officer*

Thanks, Peter.

As recently noted by Eric Topol and Steve Quake, one of our advisors, we are at the dusk of an extraordinary time in medicine wherein clinical practice will completely be transformed by applying a powerful new genomic technology.

First and foremost, Peter, R&D is on schedule at the end of April to transfer to our CLIA laboratory an accurate, robust, quantitative next-gen sequencing assay to measure donor-derived cell-free DNA from solid organ allografts. An analytically valid assay will be available from our CLIA laboratory in December of this year.

In the development of the proprietary assay, we followed clear regulations and next-gen sequence guidance from such medical organizations as the National Institute of Standards and Testing, the American College of Medical Genetics, the College of American Pathologists, as well as the Clinical and Laboratory Standards Institute. The targeted 266 SNP NextGen test on the Illumina MiSeq fulfills the carefully and specifically selected criteria for this application.

For example, the assay has to accommodate a small size, only about 160 base pairs of the cell-free DNA, as well as have the sensitivity, specificity, and precision to actually measure very low levels of cell-free DNA derived from the donor organ. Although conceptually similar to next-gen applications using cell-free DNA in non-invasive pre-natal testing, the levels of allograft cell-free DNA appear to be significantly lower than the levels observed for fetal cell-free DNA.

The assay was developed to detect donor-derived cell-free DNA in the range of approximately 0% to 15% extracted from plasma and filling as little as 3 nanograms per milliliter to 5 nanograms per milliliter of the total cell-free DNA. An additional design feature of the CareDx developed assay is the genotype of the donor and transplant recipient need not be performed to obtain accurate estimate of allograft being met. This approach significantly simplifies the procedure in a laboratory and circumvents the complexity of separately obtaining DNA from the organ donor.

As with all next-gen sequencing assay, bio informatics analysis is crucial. We have developed an in-house computational analysis pipeline that is more streamlined than most next-gen assays due to its targeted design. The bioinformatics pipeline uses both best-in-class open source and custom code. And we are exploring solutions that will provide the scale we expect will be needed for our CLIA laboratory.

Separate from our studies on CARGO II [for part] is described here at the International Body of Heart and Lung Transplantation in Nice and the opportunistic CARGO sample for our initial kidney study, the assay performed well using panels of reference material containing different levels of trace amounts of one individual's DNA. In an excess of another individual's DNA obtained two independent external suppliers who use different strategies to construct the panels giving us the high level of confidence in the assay accuracy.

We are very excited that the same assay may be used on all solid organ transplants with qualification perhaps that evidence [pertaining] to background levels, biological variability, and thresholds of actionability may be somewhat different.

Jim Yee will now describe for us for us the sample results. Jim.

Jim Yee - *CareDx Inc. - EVP and CMO*

Thanks, John.

As with any international study of heart and lung transplantation scientific session discussing new tools and the fight against rejection, new evidence is showing that clinical performance of CareDx's cell-free DNA assay in a subset of the CARGO II multicenter study that was presented by Dr. Crespo-Leiro from La Coruna, Spain. This CARGO II study is the largest multicenter patient blood sample depository from which donor-derived cell-free DNA have been measured, and the only one to also measure the AlloMap gene expression profiling but have the same patients into this.

Dr. Crespo-Leiro reported that donor-derived cell-free DNA was found to correlate rejection in heart transplant recipients based on this analysis. Her main hypothesis posed was can this new cell-free DNA biomarker found in circulating blood [have confirmed] whether the transplanted heart is rejecting or not. She found that the performance of the donor-derived cell-free DNA as evaluated using a standard assessment protocol, the area under the curve receiver operating characteristics or AUC-ROC was determined to be 68%. This is an estimate of the overall accuracy of the test. Cell-free was a preference state of biopsy proven rejection.

At this stage of development, this is a very encouraging performance because [the protocol] reference standard -- it is the reference standard of pathologists making a pathologic diagnosis of rejection, also is less than actually 68% agreement between pathologists.

The second hypothesis addressed in Dr. Crespo-Leiro's talk today was -- does cell-free DNA identify graft injuries earlier than the biopsy histopathology grading? And she found that, and reported that, 25 days prior to the rejection event, the levels of donor-derived cell-free DNA, it tend to be elevated. And this is suggested evidence that the cell-free DNA will be able to provide earlier detection of rejection than biopsy.

A third question that was addressed was -- does the cell-free DNA result add to the accuracy of the AlloMap test for ascertaining allograft status? And the answer to this question was that the two tests were determined to provide independent information. CareDx, therefore, in the analysis, created a first combined score that is using both donor-derived cell-free DNA and the AlloMap score together.

This combined score had a higher area under the curve. It was 78%. This was a significant increase over the -- either test alone. And said another way, the two tests together can provide more accurate information about rejection status than either one alone.

We had anticipated the two tests would be complementary because AlloMap gene expression profiling and cell-free DNA measures different physiologic processes. The AlloMap evaluates the status of the recipient from the system activation while the cell-free DNA evaluates the status of the allograft.

On Friday, a second abstract related to this CARGO II study will be presented by Jorg Stypmann from Muenster, Germany. He addresses the question -- can cell-free DNA be used to assess if a previously diagnosed and treated rejection is responding to treatment?

Seventeen patients had consecutive blood samples taken at the time of rejection diagnosis by instant pathology and [as this is] following this rejection diagnosis in treatment. Post treatment the donor derived cell-free DNA levels were found to decline by an average of nearly two-fold in patients who had an evidence of biopsy proven return to quiescence.

The cell-free DNA levels tended to decline when rejection was resolving. And in contrast, it was found that there were persistently elevated or increasing levels of cell-free DNA in situations where there was persistent rejection that's [down] by the reference of a biopsy.

A third cell-free DNA abstract will be presented on Friday by Dr. Paul Mohacsi from Bern, Switzerland. Dr. Mohacsi will address the hypothesis -- what is the biologic variability of donor-derived cell-free DNA and how does it compared to the analytical variability of the test method. These are important questions because when one establishes a new test that's a cell-free DNA it's necessary to establish a reference standard of within and between patient variability such that normal ranges for the cell-free DNA assay as provided by CareDx may be established.

The normal range established from multiple blood samples from patients without rejection, this is an important step towards defining thresholds for which donor-derived cell-free DNA level may be interpreted to indicate rejection for by [essence] status.

Together, these three abstracts that I overviewed show that donor-derived cell-free DNA may be a non-invasive marker for multifaceted aspects of the allograft status.

Data have demonstrated that this marker can differentiate rejection from quiescence and may also allow detection of rejection earlier than in the myocardial biopsy. Cell-free DNA may also be useful to track response to treatment or rejection.

Finally, cell-free DNA provides information about graft status that is independent and additive to the information provided by the AlloMap gene expression profiling test. Together, they increase the overall accuracy for non-invasive surveillance of allograft health in heart transplant recipients.

CareDx is sponsoring current studies that will further bring cell-free DNA to the heart transplant patient and health care providers. We are expanding the number of centers and patients in our observational AlloMap registry. This is an ongoing registry which focuses on probably long-term outcomes in patients who have regular surveillance that's using AlloMap.

We are also expanding a sub-study called D-OAR which adds the measurement of donor-derived cell-free DNA at the same visits during which the AlloMap surveillance test is used to manage the heart transplant recipients. These studies will provide further knowledge and confirmation of the clinical utility of cell-free DNA and AlloMap as presented in the CARGO II results earlier today.

These are the highlights of the latest activities sponsored by CareDx and its partnering physicians to bring cell-free DNA as well as AlloMap applications to patients. We are leading the way to transform long-term patient care in transplant patients by advancing cell-free DNA in addition to AlloMap as novel surveillance management solutions.

With that, I'll turn it back over to Peter.

Peter Maag - *CareDx, Inc. - President and CEO*

Thank you, Jim.

In conclusion, CareDx has proven itself a leading company in the area of cell-free DNA with the three abstracts that are accepted by the ISHLT conference organizers. Secondly, we have demonstrated that cell-free DNA combined with AlloMap results in greater sensitivity and specificity than either test has alone.

We continue to move forward with the development of cell-free DNA as an important biomarker for surveillance for solid organ transplant. We will be presenting more data at the upcoming American Transplant Congress and hope to see some of you there.

Let's now open it up for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from Bill Quirk with Piper Jaffray.

Bill Quirk - *Piper Jaffray - Analyst*

Great. Thanks, and good evening everybody. So first question from me is just considering that the area under the curve increased when you added cell-free DNA to AlloMap. Can you talk a little bit about the strategy and whether or not it makes sense to augment the current offering? I know certainly in select cases you're looking at doing cell-free DNA in heart, but is this data enough to try to push to include that in more or higher percentage of your AlloMap cases?

Peter Maag - *CareDx, Inc. - President and CEO*

Bill, thank you very much for that question. I can tell you here indeed there's tremendous excitement around the additional increase and additional data that we generated with cell-free DNA in combination with AlloMap.

You missed, however, I think, that AlloMap is just finding its way in Europe. So we're still in the early phases of adoption here in Europe. But many of our opinion leaders that have seen the data and the complementarity of the two approaches are extremely excited.

We'll now come back into [Brisbane] and think about how to make that [data] available. While we currently already have the opportunity of making cell-free DNA available through our D-OAR registry study where interested centers can include their patients in our registry and then we will collect the samples and ultimately provide cell-free DNA results.

Now these results are not yet provided for patient management. But given the excitement level here at the congress, we will need to think hard how to make that soon available to heart transplant patients because cell-free DNA seem to be a valuable addition to the management of post transplant care.

Bill Quirk - *Piper Jaffray - Analyst*

Okay. Great. And then two more questions from me. In terms of the data that suggest that cell-free DNA rises prior to biopsy-confirmed rejection events, can you speak about that attribute of that particular assay and maybe how that's incorporated into potential kidney study?

Peter Maag - *CareDx, Inc. - President and CEO*

Bill, again, I think this is a key to our strategy of identifying rejection earlier -- earlier than biopsy. But I'll turn that over to Jim Yee.

Jim Yee - *CareDx Inc. - EVP and CMO*

Now I wanted to be sure I heard the very last part of your question correctly. Could you just reiterate the final part of your question?

Bill Quirk - *Piper Jaffray - Analyst*

Certainly, Jim. So I guess the question is -- given that you're experiencing cardiac shows that cell-free DNA rises prior to biopsy-confirmed rejection. I think it's probably reasonable to assume that that will be the case in kidney as well. And so I'm just curious if you would consider incorporating that into your kidney studies initially or perhaps that's something that would be the (inaudible) sort of follow-on indication as a prognostic claim?

Jim Yee - *CareDx Inc. - EVP and CMO*

So thanks for that clarification. So you're exactly right. That is also exactly what we're doing in our new DART study. We are looking for and anticipating detection of evolving rejection in kidney earlier than the existing standard of care. So that's exactly what we intend to show in our recently initiating DART study.

Bill Quirk - *Piper Jaffray - Analyst*

Okay. Perfect. And then just last question from me and then I'll jump into queue. In terms of cell-free DNA, the comment being that you may have figured out a way to have this be a universal solid organ test rather than having to reinvent the assay for different organs, when might we see some incremental data here on some other solid organs? And maybe Peter, you answered the question with your last comment which is there will be some additional data at the American Transplant Congress. Is that soon enough to see some data in other solid organs?

Peter Maag - *CareDx, Inc. - President and CEO*

Yes. And Bill I think that's an excellent question. Last year when we went on the IPO road show we wanted to demonstrate that cell-free DNA is a meaningful marker in solid organ transplant. And we always said that in heart we'd like to demonstrate this as a proof of concept in heart, that this application -- and you heard the -- you asked Kobashigawa earlier talking about the universal applicability of cell-free DNA as a biomarker. With the data that we currently have on CARGO II, we feel very strongly that we demonstrate enough evidence that allows us to move into other solid organs.

And Jim just made a reference that our DART study will soon start. But we, as a company, are razor sharp focused on making the proof of concept in heart, going after the biggest opportunity which is kidney surveillance, and then we'll move into other solid organ transplant going forward. But the data as we've seen it today is very, very encouraging as an overall universal solid organ transplant test.

Bill Quirk - *Piper Jaffray - Analyst*

Very good. Thanks guys.

Operator

The next question comes from [Dan Leonardo] with [Berry].

Dan Leonardo - - *Analyst*

First, just a clarification. The 68% that you see, that was for AlloMap alone and that went up to 78% when you added the cell-free DNA and AlloMap, is that right?

Peter Maag - *CareDx, Inc. - President and CEO*

Right.

Dan Leonardo - - *Analyst*

Okay. And then my second question, for Jon. Jon you mentioned that the analytically valid cell-free DNA assay will be available in December. Given the data you're talking about, why couldn't it be available sooner? What are the gating factors?

John Sninsky - *CareDx, Inc. - Chief Scientific Officer*

I think there's two things to think about it. I think, first of all, we have a commitment in R&D to be able to start -- to be getting starting to get official results to give us an even higher level of confidence. And we'll use that information.

That won't be available for individual patient management, but we're going to gather that data as well. We're going to do whatever we can to accelerate the analytical validity of the assay in the CLIA laboratory, so stay tuned.

Dan Leonardo - - *Analyst*

And once you have the analytically valid assay available, you'll incorporate that into the AlloMap report or is that a separate decision?

John Sninsky - *CareDx, Inc. - Chief Scientific Officer*

I think the best way to think about it is that the -- since this is an emerging biomarker, even though we have a great deal of confidence in the performance of the assay, clinical relevance requires additional evidence. So we have to ask ourselves in the context of the different levels of evidence that support the AlloMap test and support the cell-free DNA test, how best to provide it to those who are requesting the AlloMap test. So we're going to look very closely at how best to relay that information.

Dan Leonardo - - *Analyst*

I understood. And my final question -- did you assess the specificity of the cell-free DNA assay as it relates to detecting cell-free DNA shed from an organ as a result of rejection as opposed to other reasons, the heart might be shedding cell-free DNA like infection or other problems?

Jim Yee - *CareDx Inc. - EVP and CMO*

This is Jim. At the current time, we have not had subsets of the sort. I think you're looking for -- that is part of our plan going forward in deeper mining of our existing archives as well as a reflection of new data in our -- the prospected study, looking for those other types of clinical situations of interest. In fact, we do not have specific data to report answers for you today.

Dan Leonardo - - *Analyst*

Okay.

Peter Maag - *CareDx, Inc. - President and CEO*

[Dan, I could] add how I'm thinking about it. When you look at AUCs of biopsies in post-transplant care, that biopsy as the current standard actually is reported to have AUCs in the range of 0.68 as well. And then we have demonstrated in our IMAGE trial that we have non-inferiority to biopsy.

Since we are not inferior to biopsies with AlloMap, now we're adding cell-free DNA. It kind of implies that there's a superiority association without saying it loud, right? That there is -- it implies a superiority to biopsy.

So biopsy is a very poor standard. Everybody would agree to it. With AlloMap already as good as biopsy, now with cell-free DNA we are probably opening up another [page]. That's what's triggering a lot of excitement here in the hallways in ISHLT here in Nice.

Dan Leonardo - - *Analyst*

Got it. Thank you.

Operator

Our next question comes from Nicholas Jansen with Raymond James and Associates.

Nicholas Jansen - *Raymond James and Associates - Analyst*

Hey, guys. Congrats on the data. Just two quick ones for me.

In terms of the strategy on potential pricing of this incremental accuracy that you're bringing to the table here, I believe there in the IPO road show, you talked about, perhaps, just kind of giving this away for free. And I was just wondering if the data that you got back was better than expected. How do you view about the potential for an incremental dollar add-on associated with the increase here?

Peter Maag - *CareDx, Inc. - President and CEO*

Nick, that's a very excellent question. I will continue to believe that adding cell-free DNA to our existing AlloMap offering puts us into an extremely well-positioned to displace the current stand of [traditional] biopsy.

We have a lot of opportunity to grow with the surveillance solution with AlloMap. And this type of data will just continuously make CareDx the prime company for heart transplant surveillance. Don't anticipate -- and I know where you're going in terms of having something in your model. Don't anticipate anything at this stage of increasing sales or special sales for cell-free DNA. We'll continue to make that available within our current revenue driver which is AlloMap for heart.

Very different story for kidney. I think we are very excited about the data today. And as Jon and Jim were mentioning, we are now very strongly focused on making that available as soon as possible, definitely given the strong results that we demonstrate here in ISHLT in Nice.

Nicholas Jansen - *Raymond James and Associates - Analyst*

And then just kind of on that last comment, Peter, in terms of the timeline for a kidney-available test. I think the last update that you guys gave, you kind of pushed out the timeline a little bit just in terms of how you're thinking about when revenue could kick in for kidney. Does this data change the cadence of the launch?

Peter Maag - *CareDx, Inc. - President and CEO*

No. I think we have that data in hand now, and we'll be talking about kidney a little bit more at the ATC. So that allows me, Nick, to actually just entice you to come to Philadelphia, to ATC, and we can talk about kidney launch further. But for the time being, we continue to stick to the previously communicated timeline on the kidney solution.

Nicholas Jansen - *Raymond James and Associates - Analyst*

Thanks guys.

Operator

Again, ladies and gentlemen, if you have a question or a comment at this time, please press star then the one key on your touch tone telephone. Our next question comes from Peter Lawson with Mizuho Securities.

Peter Lawson - *Mizuho Securities - Analyst*

Peter, I'm just wondering if you could tell us how many patients that the cell-free has been run on to date, either heart or kidney.

Peter Maag - *CareDx, Inc. - President and CEO*

I can't hear. It's hard to hear you. Could you speak up a little bit? It's hard to hear.

Peter Lawson - *Mizuho Securities - Analyst*

Yes. Just wondering if you could tell us how many patients have cell-free been run on to date either kidney or heart?

Peter Maag - *CareDx, Inc. - President and CEO*

Really, Jon, do you know how many total cell-free DNA samples we have run?

I will try to structure this into four sample sets that we've analyzed. We have the CARGO II sample set that we analyzed. We have the [CARGO] sample sets that we analyzed. We have the ongoing D-OAR sample sets. And then we have sample sets to be used for analytical validation.

John, do you have anything from -- what's the number of tests that we run on?

John Sninsky - *CareDx, Inc. - Chief Scientific Officer*

I would approximate in the range of 1 to 200 samples in each of those subsets Peter has said. But with the overall total, in the range of 500-ish in total.

Peter Maag - *CareDx, Inc. - President and CEO*

So the answer, Peter, is 500 cell-free DNA samples.

Peter Lawson - *Mizuho Securities - Analyst*

Thank you. And I may have missed this, but when do you expect data from the D-OAR study? And would we get initial DART data at the end of '15?

Peter Maag - *CareDx, Inc. - President and CEO*

The D-OAR study, that's a very good question, Peter. But since it is a registry study, it actually allows us to continuously generate data, and that's if the data comes in. We engage with our key opinion leaders in the field of heart transplant -- how are they thinking and how are they using this data.

The D-OAR study, we have been updating about the progress. Last night, we had an Investigator Meeting here at the ISHLT Nice meeting. And the number of interest into joining the D-OAR study and expanding into cell-free DNA has rapidly increased based on the data that we see.

So, Jim, maybe you want to add to that.

Jim Yee - *CareDx Inc. - EVP and CMO*

Yes. I think at some of the previous reports, Peter (inaudible) specific numbers of how many samples in cell-free DNA had been collected from the D-OAR study, and it was a modest number.

What I'd like to say based on our Investigator Meeting last night is we have a substantial growth in study anticipated for the remainder here in a number of centers starting up and [sizable centers] which have a relatively high volume of patients.

So we anticipate by the end of this year, we will have accumulated significantly larger numbers than we've reported so far. As Peter said, our plan is no less often than about yearly we will be doing interim analysis on what we've learned from the accumulating samples.

Peter Lawson - *Mizuho Securities - Analyst*

Thank you. And just wondering if you could talk through the clinical relevance of this 10% improvement in combining both tests. How significant is that? And do you think that will drive physicians into using the test?

Peter Maag - *CareDx, Inc. - President and CEO*

I'll let Jim talk talk to it. But I think, Peter is just asking around the 0.68 to the 0.78 and what does that clinically mean.

I can tell you that from my perspective and the excitement level that I hear at the conference, it's very substantial. But, Jim, how does one think about the additional [complementarity] of the test?

Jim Yee - *CareDx Inc. - EVP and CMO*

Yes. I think there is a lot of encouragement and optimism by the cardiologists who are hearing about this. A 10% increase in this range of going from the 70%, 80% accuracy is quite clinically meaningful and relevant. Those who are involved with test development, it's unusual to find additive tests that really are providing what we call orthogonal information. And so those are the aspects that cause a lot of strong interest in this.

So I would say the [expectation] is -- there is a very strong interest in this incremental increased accuracy which are complementary dimensions of assessing the status of the allograft.

John Sninsky - *CareDx, Inc. - Chief Scientific Officer*

This is John here. I think my answer to that is that on a first [test] that combined the AlloMap and the cell-free DNA, we really wished (inaudible) preliminary. And our expectation is more detailed kind of algorithm that looks at differential waiting, for instance, for each one of those. We may even find that the test has even higher performance (inaudible) tests and even higher performance relative to AlloMap.

So it's really early days. So stay tuned.

Peter Lawson - *Mizuho Securities - Analyst*

Okay. Thank you so much.

Operator

And this concludes the question and answer portion of today's conference. I'd like to turn the call back over to Peter for any closing remarks.

Peter Maag - *CareDx, Inc. - President and CEO*

Well, thank you very much. Great questions, and looking forward for additional and future discussions. Next will be our quarterly update. And then, obviously, we are very excited about the American Transplant Congress in Philadelphia.

Well, thank you very much for your interest. And thank you. Thank you.

Operator

Well, ladies and gentlemen, this thus concludes today's presentation. You may now disconnect, and have a wonderful day.