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SPHS - Sophiris Bio Inc Reports Successful Results from Completed Phase 2a Study of Topsalysin in Localized Prostate Cancer Call

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JUNE 09, 2016 / 09:00PM GMT, SPHS - Sophiris Bio Inc Reports Successful Results from Completed Phase 2a Study of Topsalysin in Localized Prostate Cancer Call

CORPORATE PARTICIPANTS

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Randall Woods *Sophiris Bio, Inc. - President and CEO*

Allison Hulme *Sophiris Bio, Inc. - COO*

Hashim Ahmed *University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study*

CONFERENCE CALL PARTICIPANTS

Jason Kolbert *Maxim Group - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome Sophiris Phase IIa Prostate Cancer Data Investor Webcast Conference Call. At this time, all participants are in a listen-only mode. (Operator Instructions).

As reminder, today's conference may be recorded. I would like to introduce you host for today's conference, Mr. Peter Slover, Chief Financial Officer of Sophiris. Sir, please go ahead.

Peter Slover ***- Sophiris Bio, Inc. - CFO***

Thank you for joining us on todays' call. On the call today, we intend to discuss the six-month biopsy data for all 18 patients in our Phase IIa study on topsalysin in men with localized prostate cancer. Details were announced earlier today in a press release now available on our web site at www.sophiris.com.

Joining me on today's call with prepared remarks are Randall Woods, our President and Chief Executive Officer; and Allison Hulme, our Chief Operating Officer and Head of Research and Development. We are also joined by Dr. Hashim Ahmed, who in the principal investigator for the Topsalysin Localized Prostate Cancer Study at the Division of Surgery and Interventional Sciences at the University College London in the U.K.

Before we begin, I will remind you that certain information including any information that is not historical information, including statements about future clinical trials or clinical trial results and statements about further development of topsalysin for the treatment of localized prostate cancer or symptoms of BPH constitute forward-looking statements that are subject to risks and uncertainties relating to Sophiris' future financial, clinical, or business performance. Actual results could differ materially from those anticipated in these forward-looking statements. Risk factors that may affect results are detailed in Sophiris' filings with the U.S. Securities Commission, which can be accessed at www.sec.gov. Please note that Sophiris is under no obligation to update any forward-looking statements discussed today except those required by law, and investors are cautioned not to place undue reliance on these statements.

Regarding the agenda for today's call, Randy Woods will provide introductory comments. Dr. Hulme and Dr. Ahmed will then discuss the details of our Proof of Concept Study in Localized Prostate Cancer. Randy will then provide closing remarks

I'll now turn the call over to Randy. Randy?

Randall Woods ***- Sophiris Bio, Inc. - President and CEO***

Thank you, Peter. I'm very excited to be reporting the results from our Phase IIa Study with our shareholders today. Data from our clinical program continues to indicate that we have a clinically meaningful drug candidate with potential to impact patients suffering from two distinct urological diseases, those being localized prostate cancer, meaning prostate cancer that has not yet metastasized, as well as BPH more commonly known as enlarged prostate.

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Topsalysin demonstrated an ability to ablate tumor cells in 50% -- nine out of 18 patients -- six months after treatment in a patient population with pre-identified clinically significant prostate cancer. This includes two cases of complete tumor ablation with no evidence of any tumor remaining. This clear indication of biological activity with very little in the way of side effects and prior to defining dose and optimal delivery is very encouraging. It increases our confidence in the potential of topsalysin as a novel therapeutic in localized prostate cancer with the potential to delay or even avoid radical therapy. We plan to advance the program into a dose and delivery confirmation study prior to moving into a Phase III registration study.

The focus of today's call is on the Phase IIa Proof of Concept Study in Localized Prostate Cancer. But for those on the call who are new to the story, I do want to briefly call attention to our Phase III study of topsalysin as a treatment for BPH that successfully met its primary endpoint. We reported that data last November and discussed it in detail via a webcast in January. A replay and transcript are available on our web site.

Altogether, Sophiris has developed robust topsalysin data package demonstrating a favorable safety and tolerability profile as well as clear therapeutic activity with clinically meaningful benefit in patients with BPH and a very encouraging signal that we can ablate prostate tumors in patients with localized prostate cancer. We are excited about the opportunities for the Topsalysin Programs which have been generating attention from both clinicians and industry.

With that, I would like to turn the call over to Dr. Allison Hulme and Dr. Hashim Ahmed to provide more details regarding the data from the Prostate Cancer Program reported today. Allison, please go ahead.

Allison Hulme - ***Sophiris Bio, Inc. - COO***

Thank you, Randy. First of all, I'd like to provide a little background on the dilemma of patients diagnosed with localized prostate cancer face and the solution that we believe topsalysin could represent. On our Investor Call in January, we discussed the two extremes of care that men with localized prostate cancer faced -- one, they may choose to enter active surveillance in which they receive no treatment but undergo periodic PSA testing and periodic or as indicated prostate biopsy; or two, they may decide to undergo radiation of their prostate or even complete surgical removal of the prostate often with substantial and permanent quality of life side effects, such as urinary incontinence, erectile dysfunction, and rectal toxicity.

More recently, an alternative approach offered to some patients is the use of targeted focal treatment of their localized disease. The goal is to remove the tumor and preserve as much of the organ as possible; thereby reducing the toxicity associated with the whole gland treatment and preserving the quality of life. Increasing the use – increasing use, sorry, of multiparametric MRI along with advances in software that maps this previously obtained MRI images to real-time ultrasound images now enables physicians more accurately locate tumors within the prostate when taking their biopsy; thereby increasing the accuracy by which men with clinically significant lesion are identified.

These advancements in imaging and the associated software technology create a novel opportunity for highly potent ablative agent such topsalysin. We can now inject topsalysin directly into and around a pre-identified clinically significant tumor. We can then use the same technology to visualize the tumor site after treatment to accurately biopsy and then measure the response to treatment.

The results of the Phase IIa study validate this approach. They also increase our confidence that topsalysin can become a focal targeted therapy (technical difficulty) ablation of localized prostate cancer while avoiding many of the complications and side effects associated with the radical treatments that are aimed at the entire prostate.

We initiated this Phase IIa Proof of Concept Open-Label trial in patients with clinically significant localized prostate cancer at the single-center in the United Kingdom, the University College London, with two world renowned experts in the so called treatments of localized disease, Drs. Mark Emberton and Hashim Ahmed.

Dr. Ahmed, who has so kindly joined us today on the call, is the principal investigator for this proof of concept study and has personally administered topsalysin to all of the 18 patients that we enrolled in the study. Dr. Ahmed has also participated on FDA and other regulatory healthy authority panels advising on how best to move the whole field of focal treatment of clinically significant localized prostate cancer forward.

I would now like to turn the call over to Dr. Ahmed to talk more about the proof of concept study.

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

Thank you, Allison. It's a pleasure to join you today.

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Allison Hulme - ***Sophiris Bio, Inc. - COO***

Thank you.

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

This is a nice end to a busy week at the ASCO Annual Meeting in Chicago. In the study, we entered patients who had an MRI visible lesion, which was confirmed to be clinically significant by targeted biopsies. It is important to note that each patient in the study warranted treatment based on the clinical risk factors.

The previously obtained multiparametric MR images of clinically significant lesions were mapped to real time three-dimensional ultrasound images using an elastic image-fusion software to facilitate the injection of topsalysin into and around the pre-identified lesion. The primary objective of the study was to assess the safety and tolerability of the administration of the higher total dose of topsalysin, up to 5 microgram per gram of prostate compared to the lower dose of 0.6 microgram per gram of prostate used in the successful Phase III BPH study.

As Allison stated, we treated eight [18] patients with clinically significant prostate cancer with various doses of topsalysin or greater than what was given in the BPH Program. No serious adverse events were observed and no new safety signals reported. The safety observed in this Localized Prostate Cancer Study is consistent with that observed in the 365 patients that have been treated in the company's BPH Program.

The key efficacy variable for the study is the change in the treated lesion on biopsy after six months. Of the 18 patients enrolled, all patients completed the study and biopsy data at six months following treatment showed that topsalysin was able to ablate tumor cells in nine of the 18 patients we treated.

Two men experienced complete ablation of the tumor with no evidence of tumor remaining on the targeted biopsy at six months. Seven men experienced a partial response, defined as either a reduction in the maximum cancer core length, the amount of cancer within a biopsy, or a reduction in the Gleason pattern. The other nine patients had no response to treatment. Some of these men we observed continued tumor with tumor progression, indicating that we did indeed have the appropriate patient population that required treatment. In this proof of concept study, we learned that in certain tumor types, we were either not administering a high enough dose or we're not delivering the drug to enable it to stay in and around the tumor; both of which we believe are correctable in future studies.

Importantly, the patients that did not respond can now safely progress or have other treatments and be offered another focal therapy, or in some cases, they may opt for a radical treatment. These results are encouraging, and in some cases, exceeded expectations. We expected to see biological activity and signs of tumor reduction, but this Proof of Concept Study was really designed to help generate experience so we can define the dose and the optimal delivery for future clinical studies. Even without having a confirmed dose and delivery, we saw clear evidence of tumor ablation in half of the patients treated. Impressively, two patients had complete ablations in the small trial which is very promising.

We will continue to review the data from the study, but we believe we have identified a way forward with dose and we will be dosing based upon the size of the tumor in the region of 1,000 micrograms per gram of tumor. In other the words, we will individualize the dose based on the size of the patient's pre-identified tumor and not based on the size of the prostate as was the case in the BPH Program. We also have plans to optimize the delivery of topsalysin by attaching the injection needle to an infusion pump or potentially using a porous tip needle that we have identified.

The goal being is to slowly administer the drug, allowing it to diffuse into the tumor cells and the surrounding area. With these learnings, we believe that we should be able to increase the consistency of response in the next study. I look forward to confirming this approach in the future clinical study.

In summary, topsalysin has shown a clear ability to ablate cancer cells and appears to be well tolerated with few side effects. We have also learned a lot from the study for optimizing the dose and the delivery so that we may potentially improve upon these outcomes in the future. This presents an exciting and much-needed opportunity to treat the patients who have clinically significant localized prostate cancer with topsalysin, ablate pre-identified lesions, and downgrade the patient to nonsignificant cancer. This would be extremely clinically meaningful for men as it may help them either avoid or delay the need for radical therapies and significant side effects associated with radical therapies.

I'd now like to turn the call back over to Sophiris.

Randall Woods - ***Sophiris Bio, Inc. - President and CEO***

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Thank you, Dr. Ahmed, for taking time out of your busy schedule to be with us today. The work you and the entire team at University College London have done has just been exceptional. I also want to take this time to thank the patients and their families that have participated in the study. Its these types of results and the potential benefit of patients that inspires and motivates us to bring topsalysin closer to market.

Topsalysin is a novel, first in class treatment for localized prostate cancer. The encouraging activity in localized prostate cancer opens up a new opportunity for patients faced with the difficult decision of the treatment with radiation therapy or with a complete surgical removal of their prostate, both of which present with significant life-altering side effects.

Topsalysin represents the potential win for patients faced difficult treatment decisions, for physicians with limited early treatment options, and for payers looking to temper the cost of care. The results and learnings reported today give us confidence and supports our plan to aggressively advance topsalysin into a Phase II dose and delivery confirmation study in localized prostate cancer subject to securing additional funding. The study can be undertaken quickly and would enable us to optimize the delivery and dose of topsalysin to ablate targeted tumors prior to initiating a Phase III Registration Study.

We announced last month that we engaged Oppenheimer to advise on strategic options for moving the Topsalysin Programs forward. With the strength of all the data across the BPH and Prostate Cancer Programs, we believe we are in a good position to have multiple options for advancing these programs forward. These options could include potential partnering arrangements, financings, or a strategic transaction.

Before I close, I'd would like to thank our shareholders for their continued support, especially those who have been with us on this journey for a long time. Your belief and the incredible potential of topsalysin is appreciated. We have generated positive momentum with the string of positive data results, and we look forward to continuing that progress.

This concludes our formal remarks. I'll now turn the call back over to the operator.

QUESTION AND ANSWER

Operator

Thank you. (Operator Instructions)

Our first question comes from the line of Jason Kolbert with Maxim. Your line is open. Please go ahead.

Jason Kolbert - ***Maxim Group - Analyst***

Hi, guys. I'm very excited for you as well and for us, for men. It is a great data. Help me understand a little bit about what dosing changes you think would make a difference in the next study and also I'm very intrigued when you talk about delivery option. So, help me understand a little bit when we're talking about a very small detected localized cancer. How do you figure out exactly where to inject topsalysin? And how might you change the delivery methodology going forward?

And then last part of the question is, tell me -- help me interpret the clinical value? Again, you touched on this a little bit in terms what it means to see a 50% response rate in an n equals 18 trial, how might those numbers change in a more optimized setting? And I realized that speculating but I'm just trying to understand clinically how you interpret this data. Thanks.

Allison Hulme - ***Sophiris Bio, Inc. - COO***

So, Hashim, would you --

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

Allison, do you want to do the dose and I can do the delivery? And then perhaps the two of us can answer the potential impact that might have on the subsequent study. You --

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(Crosstalk)

Allison Hulme - ***Sophiris Bio, Inc. - COO***

Okay. So if I start --

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

-- dose and I'll do the delivery.

Allison Hulme - ***Sophiris Bio, Inc. - COO***

Yes. No worries. So, I'll start up from the dose then. Jason, thank you to your question. What we know from this proof of concept study is that the patients are being identified with different sizes of tumor. And although we dosed individually based on the size of the prostate in BPH, we did not make that adjustment in this proof of concept for dosing on the size of the tumor. And what has become apparent through the 18 patients that we have treated is that there is a trend that across the different sizes of tumor that we have treated for a dose in the order of a 1,000 micrograms per gram of tumor to be the dose that does give us ablation of tumor cells.

So, we did not in the study start off with dosing on tumor size and individualizing at the tumor size. That is definitely something the data have taught us that we will need to do going forward.

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

Jason --

Jason Kolbert - ***Maxim Group - Analyst***

That makes perfect -- sorry, that makes perfect sense, that adjusting dose for tumor size allows a better response rate. But in the nine nonresponders, do you think there was a bit of a mismatch there?

Allison Hulme - ***Sophiris Bio, Inc. - COO***

I think yes, the data would indicate that there was and that they were below the 1,000 micrograms per gram of tumor, Jason, and also we do detect that there may be something in how we deliver and I'll let Hash speak to that in a moment. But I do think it's quite clear from nonresponders that we were not getting enough drug into or around the tumor.

Jason Kolbert - ***Maxim Group - Analyst***

Allison, thank you.

Allison Hulme - ***Sophiris Bio, Inc. - COO***

You're welcome.

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

I think the --

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Allison Hulme - ***Sophiris Bio, Inc. - COO***

Hash, would you like to comment on the [frequency]?

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

Yes. The three questions are really, really good questions. The delivery I think is the other factor. And we've learned -- as the study was designed, we learned more about the delivery and the dosage as we wanted to in order to optimize what we're going to do in the next study. So, the way I was delivering the drug in this study was to inject it myself very slowly into the tumor based on the image fusion platform identifying where lesion was.

And I think it became very apparent that certain tumors, and when I was injecting them, the drug wasn't necessarily staying where it should be, where I was injecting. And tumors are more dense, and what I think we will need to do going forward and what we've learned over these 18 cases is that the drug needs to be diffused into the tumor much more slowly. And I think the only way to control for that and get it disseminated across a number of centers across users, the only way to control that is to connect the drug delivery to an infusion pump which, for instance, will infuse the drug very slowly over a time period, which allows the drug to then diffused all of the cells within the tumor. And we think staying near the center of the tumor with two or three needle insertions is going to be better than lots of needle insertions in order to deliver drug. So, it is allowing an opportunity for the drug to permeate through all of the cells in a very slow fashion.

Jason Kolbert - ***Maxim Group - Analyst***

And that also makes perfect sense because these are micro tumors. It's not like there is vasculature that you could go to. So, by bathing the area with two or three injections over a long period of time, you're going to try to just saturate the tumor versus trying to hit with a rifle shot. Am I thinking of it the right way?

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

Absolutely. So -- and when I was doing some of the injections, you could see -- despite the fact that I was being very slow, I think ultimately an infusion pump will be able to control that delivery, and as you say, bathing is a very apt description of what we're trying to achieve going forward.

Jason Kolbert - ***Maxim Group - Analyst***

Okay. That's very helpful, and just the last question, if you could just step back and help me understand and you touched on this earlier, the clinical significance. I mean one of the things that you mentioned is that some men are put in a situation where they have to wait and watch. But what I hear you saying is that by offering a therapeutic alternative that has no adverse events, you have a chance to kind of put something into check and even from a physician paradigm or for patients something more aggressive than just waiting and watching. Is that kind of how you look at it as well?

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

Yes. So, I think there's two types of benefit that men can derive. One is that the treatment can eradicate the lesion that we want to eradicate and we saw that in two patients. And we would be aiming to replicate that as much as possible in subsequent study. In addition in a much larger group of patients where we can take them from a clinically significant lesion that warrants treatment and usually and often these men are having or choosing or being recommended to have radical therapy. If we can take that man from a status of significant cancer that warrants radical therapy at the moment which carries its side effects, to status of insignificant cancer that warrants surveillance but in a very safe way without the complications and side effects of radical therapy, then I think that would -- that is going to be a major plus, a clinically meaningful patient relevant outcome on both of [those fronts].

Jason Kolbert - ***Maxim Group - Analyst***

Thank you so much for the for update. And, Allison, Peter, and Randy, really congratulations. This is great stuff.

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Randall Woods - ***Sophiris Bio, Inc. - President and CEO***

Thanks, Jason.

Hashim Ahmed - ***University College London - Principal Investigator, Topsalysin Localized Prostate Cancer Study***

Thank you.

Allison Hulme - ***Sophiris Bio, Inc. - COO***

Thank you.

Operator

Thank you. And I'm showing no further questions at this time. And I'd like to turn the conference back over to Randall Woods for any further remarks.

Randall Woods - ***Sophiris Bio, Inc. - President and CEO***

Thank you, everyone, for joining us on the call today. We're delighted about these continued good results with topsalysin, and we look forward to providing an update for all of you later this year. Thank you very much.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program and you may all disconnect.

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