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Sophiris Bio Inc provides interim Topsalysin Phase 2b Clinical Trial Update

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PRESENTATION

Operator

Good morning and welcome to Sophiris Bio's conference call to discuss interim top line efficiency and safety planning for its topsalysin Phase 2b clinical trial in localized prostate cancer.

As a reminder, today's call is being recorded. It is my pleasure to introduce Peter Slover, Chief Financial Officer of Sophiris.

Peter Slover *Sophiris Bio - CFO*

Thank you, Operator.

Good morning everyone and thank you for joining us. Earlier today, we issued our press release providing an overview of the topline interim safety and biopsy results following a single administration of topsalysin in an ongoing Phase 2b clinical trial in the treatment of localized prostate cancer.

The press release can be viewed by visiting the Investor Relations section of our website at www.sophirisbio.com. Joining me on today's call 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 Professor Hash Ahmed who is the Chief Investigator for this Phase 2b study as well as the previously reported Phase 2a proof-of-concept study. Professor Ahmed currently serves as the Chair of Urology and Consultant Urological Surgeon at Imperial College Healthcare NHS Trust and Professor of Urology, Imperial College of London.

Before we before we begin I will remind you that certain information including any information that is not historical information including statement about feature clinical trials or clinical trial results and statements about further development of topsalysin in the treatment of localized prostate cancer constitutes forward-looking statements that are subject to risk and uncertainties related to Sophiris' future financial clinical core business performance.

Actual results could differ materially from those anticipated in these forward-looking statements. Risk factors then 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 statement discussed today except those required by law. And investors are cautioned not to place undue reliance on these statements.

During today's call, Randy will first provide introductory comments. Dr. Hume and Dr. Ahmed will then provide additional color on the interim safety and biopsy data following an administration of topsalysin from the Phase 2b study.

At this time, it is my pleasure to turn the call over to Randall Woods.

Randall Woods *Sophiris Bio - President and CEO*

Thank you, Peter. And good morning, everyone. Thank you for joining us today.

As promised, we wanted to share with you before the end of this quarter the interim safety and biopsy data from a single administration of topsalysin to a pre-identified targeted lesion that warranted treatment.

Before providing data though, I want to mention as announced in our press release that we were recently notified by one of our clinical investigators in the U.S. that a patient died on the same day he received the second administration of topsalysin. I would like to offer our condolences to the patient's family at this difficult time.

We are currently investigating the cause of death. And as a precaution, the remaining two patients will not receive a second administration of topsalysin in the Phase 2b clinical trial.

Prior to this event, 10 additional patients were retreated. Those 10 retreated patients will continue to be monitored and six-month followup biopsies will be collected and analyzed per the study protocol.

Now, with regard to this data, 38 patients with pre-identified clinically significant localized prostate cancer were enrolled in our Phase 2b clinical trial across eight sites in Europe and United States. Patient safety is of the utmost importance to us, and to date, over 450 patients have been treated with a single administration of topsalysin at various doses.

The primary objective of this study was safety and this initial data suggest that topsalysin continues to demonstrate a favorable safety profile after a single administration.

The safety and biopsy data from those patients receiving a second demonstration of topsalysin will be available by the end of this year as previously notified.

A secondary objective of the study was to evaluate the efficacy of topsalysin to treat the preidentified lesion as assessed by a targeted biopsy of the treated area six months after a single administration of topsalysin.

At the time of this release, follow-up targeted biopsies have been evaluated from 35 of the 38 patients treated. Two of the remaining patients are expected to undergo follow-up biopsies in the coming weeks.

Based on these follow-up biopsy results, we are happy to announce that topsalysin demonstrated a clinical response in 10 of the 35 patients for 29%. Six of the 10 clinical responders experienced a complete ablation of their treated lesion, meaning there was no histological evidence of the tumor remaining on the targeted biopsy.

This compares favorably to the 3 out of 18 patients for 17% of the patients who had a clinical response in the Phase 2a trial where two patients experienced a complete ablation.

We are very pleased with the initial biopsy results presented today. These data build and expand on the Phase 2a proof-of-concept trial results and key findings we reported in June 2016 and give us confidence that topsalysin can ablate prostate cancer cells as we work towards the next stage of development to ultimately make topsalysin available for men with clinically significant localized prostate cancer.

The safety and tolerability of the single administration of topsalysin from this study remain in line with what we have seen historically. Importantly, the biopsy results continue to improve on what we saw in the Phase 2a proof-of-concept trial.

We and our scientific advisors believe that safety and biopsy data from the first administration of topsalysin supports moving forward into potential registration studies. We will continue to evaluate whether future clinical development will include an option to administer

a second dose as we receive more information about the patient death and additional information from the 10 patients who received a second dose. This should be available by the end of the year.

With that, I would like to turn the call now over to Dr. Allison Hulme. Allison, please go ahead.

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

Thank you, Randy.

Before Professor Ahmed takes us through a more in-depth review of the interim safety and biopsy data from the single administration of topsalysin from this ongoing study, let me outline for you why we believe that topsalysin has the potential to provide men who are diagnosed with clinically significant low to intermediate risk disease with a targeted treatment to control that prostate cancer while preserving their prostate gland and thereby avoiding many of the commonly occurring side effects associated with traditional approaches of surgically removing the prostate or from radiation.

First of all, we are now able to diagnose men with clinically significant localized disease with much greater certainty due in part to increase use of multi-parametric MRI and advances in the software to co-register previously obtained MRI images with real-time ultrasound images. Enabling targeted biopsies of suspicious areas within the prostate as opposed to relying on a random biopsy of the prostate.

The same technology, equipment, and expertise developed by the physician to target areas of the prostate for biopsy can also be used to deliver an intraprostatic injection topsalysin to a preidentified lesion that has been confirmed by histopathology to be clinically significant.

In addition, topsalysin has been specifically designed to only be activated when it comes into contact with enzomatically active PSA which stand in high concentrations around prostate tumors. Once activated, topsalysin causes a pore to be formed in the cell membrane of the tumor cells causing cell death by lysis of the cell contents while preserving the remainder of the prostate and surrounding structures.

So, in summary, we believe that the targeted mechanism of action of topsalysin, together with the targeted delivery means that topsalysin could have the potential a valuable treatment option for men with clinically significant low to intermediate risk prostate cancer controlling or ablating the targeted tumor could delay the need for radical and invasive treatments, or in some men, even eliminate their need completely.

I would now like to just recap on a couple of the important learnings that we had from the previously completed Phase 2a proof-of-concept study. In the proof-of-concept study, we learned that certain patients will potentially, even not administering sufficient topsalysin or the delivery of the drug was not sufficient to enable it to reach and stay in and around the targeted tumor.

These learnings, like the two of the most important changes that we incorporated into our ongoing Phase 2b protocol. First, we now individualize the dose of topsalysin based on the five of patients preidentified tumor rather than the size of the prostate as with the case in the BPH program and the proof-of-concept prostate cancer trial. Dosings of this Phase 2b trial was capped at a 1,000 micrograms per gram of tumor with a goal of delivering approximately 500 to 1,000 micrograms of targeted tumor.

Secondly, in the proof-of-concept study, topsalysin was actually manually injected by Professor Ahmed who was the chief investigator and it was noted on several occasions by him that depending upon the density of tumor being injected, microjets would set up a backwash of the drug away from the tumor could be observed with the study drug not having the opportunity to actually penetrate the tumor being injected.

Therefore, we felt it was important to administer the drug more slowly so that it could diffuse into the tumor cells and in the current study, would move away from a manual injection and now attach the injection needle and syringe to a mechanical spring-loaded infusion pump known as spring fuser. The spring fuser controls the rates of delivery by applying a fixed amount of pressure which enables a more

controlled and consistent delivery of topsalysin.

Even with the addition of the new delivery approach, administration of topsalysin can typically be completed in 10 minutes.

With that, I would now like to turn the call over to Dr. Ahmed who is the Chief Investigator for the trial as well as being that role in the proof of concept Phase 2 study in prostate cancer. Dr. Ahmed has also participated on FDA and other regulatory health authority panels, advising on how best to move the whole field of focal of clinically significant localized prostate cancer forward.

Dr. Ahmed?

Hashim AhmedThank you, Allison. I'm glad to have the opportunity to speak to you all today.

Let me start by thanking the investigators, study staff and patients of the eight clinical sites that are participating in the study. We have four sites in the U.K. including my own team at Imperial and another four sites located in the U.S. and have a [approved] just 38 patients combined with low to intermediate risk clinically significant localized prostate cancer.

Patients entered in the study had an MRI-visible lesion which was confirmed to be clinically significant by targeted biopsy. It is important to note that each patient in the study warranted treatment rather than active surveillance based on the clinical risk factors.

The previously obtained multiparametric MRIs of the clinically significant lesion were matched to real-time three-dimensional ultrasound images using the elastic image fusion software called SmartTarget to facilitate the injection of topsalysin into and around the preidentified lesion.

For this study, I also acted as the central study treatment reviewer. What does this mean? In this role, I would review the multiparametric MRI images for a proposed patient. The contouring of the prostate and the contouring of the proposed lesion for targeting together with the histopathology report and then approved the proposed treatment plan.

This enabled me to share my experience and hep train each of the injecting physicians across the sites and also allowed us to standardized the injection approach. Ultimately, though, the final responsibility on injecting the targeted lesion was left to the injecting position.

The primary objective of the Phase 2 study was to assess the safety and tolerability of a single administration of topsalysin. Unlike the previous study, this time, we dosed patients on the size of the lesion with cap of 1,000 microgram per gram of targeted lesion which was the highest dose we administered in the proof-of-concept study.

The safety analysis to date following a single administration indicates that topsalysin has been well tolerated. There were no new safety signals following a single administration. No hypersensitivity reactions or other serious systemic reactions to study medication were observed after a single administration.

Adverse events considered related to topsalysin and occurring in more than one patient were dysuria, three patients; urinary retention, three patients; nocturia, three patients, micturition urgency, two patients, and strained urine, two patients.

All adverse events were considered mild and typically result within the same day with the exception of one event of micturition urgency which was considered severe and was resolved the same date. And one event of urinary retention which was considered moderate in the event considered resolved after the patient underwent a transurethral resection of the prostate, otherwise known as a TURP.

A secondary objective of the study is to evaluate the efficacy of a single administration of topsalysin determined by a targeted biopsy of the treated lesions six months post dosing.

Two date, targeted biopsies have been undertaken and evaluated from 35 of the 38 patients treated with the single dose of topsalysin.

Two of the remaining patients are expected to have a targeted biopsy in the coming weeks.

So, do the changes that we made to this study targeting a lesion with up to 1,000 micrograms of topsalysin and changing the delivery from a manual injection to a slow mechanical spring-loaded diffusion help? Based on the six-month followup biopsies, 10 of 35 patients or 29% demonstrated a clinical response defined in this study as no detectable tumor on targeted biopsy of the treated lesion or a sufficient reduction to deem the lesion clinically insignificant.

What do we mean when we say clinically insignificant? Effectively, the treated tumor can be considered as no longer requiring further treatment and the patient could be monitored in active surveillance.

In this study, clinically significant -- clinical insignificant was defined as a cancer lesion with a Gleason Score of 6 and a maximum cancer core length or MCCL of less than 6 mm.

This result compares favorably to the 17% of patients 3 of the 18 patients who moved to clinically insignificant disease in the previously completed proof-of-concept study. Of the 10 clinical responders we had in this, trial patients have a complete ablation with no histological evidence of the tumor remaining. This compares with just two patients in the proof of concept study we previously carried out.

Additionally, the Phase 2b single administration followup biopsy data that 13 of 35 patients or 37% experienced a partial response which we defined as a reduction in MCCL, maximum cancer core length, and/or Gleason pattern but the targeted lesion were still deemed clinically significant. So, in these patients, we were still able to ablate some of the lesion.

Finally, 12 of 35 patients or 34% of patients did not respond to treatment defined as no change in the targeted lesion or an increase in MCCL and/or Gleason pattern.

These initial biopsy results released today following a single intraprostatic administration of topsalysin are highly encouraging and definitely improve upon the proof of concept study results with a greater proportion of patients experiencing successful treatment of their treated lesion. Most importantly, we have shown that a single administration of topsalysin continues to appear safe and well tolerated.

Additionally, use of the spring infusion system to deliver the drug has not significantly increased the time to administer topsalysin which typically takes around 10 minutes with the whole procedure being completed in approximately 30 minutes. Furthermore, we have shown that targeted focal therapy with topsalysin in this patient population is transferable to other clinicians which is encouraging as we think about designing large multicenter global studies.

At least half of the participating clinical sites observed patients with no detectable lesion on rebiopsies of the targeted tumor and all eight sites observed patients in which lesions were at least partially ablated.

Within our own team, we have spent a lot of time discussing what type of response rates we are looking for and how we define a positive outcome for a trial in these localized prostate cancer population. When we set out for the Phase 2b trial, we believed that to achieve a 30% clinical response rate would be very encouraging.

If the results were to be replicable in the Phase 3 trial, it suggests that treatment with topsalysin can help almost a third of patients potentially delay or completely avoid a more invasive therapy.

In summary, we continue to be encouraged that we can safely ablate a targeted tumor with a single administration of intraprostatic topsalysin. The procedure is short with a total duration of approximately 30 minutes and for some patients can be undertaken in an office or ambulatory setting.

As we have seen from the safety data of a single administration, patients appear to tolerate the procedure extremely well. Secondly, the administration is transferable to other centers with a short learning curve for physicians that probably had more to do with using a

standard fusion software in the trial. Looking forward, we can minimize that by allowing the treating physician to utilize whatever fusion software they are familiar with when undertaking their targeted biopsies.

Thirdly, we do want to work on the delivery of the relatively slow diffusion achieved with the spring fuser. This is definitely an improvement, but for some lesions, we may want to use a slightly larger volume than the 6 milliliters that we used in the study.

And finally, there definitely continues to be an unmet need to provide men with clinically significant low to intermediate risk disease with targeted focal therapies aimed at controlling their cancer whilst preserving the prostate and thereby potentially avoiding toxicities associated with whole gland therapy.

Continuation of the development of topsalysin is definitely warranted, and indeed, we have been working on what a potential registration study would have to look like with both regulators and medical experts in the field. It is to soon to say in what that would look like but something that we are working on.

With that, I'd like to turn the call back over to Randy for final comments.

Randall Woods ***Sophiris Bio - President and CEO***

Thank you, Professor Ahmed.

It is evidence that there is a tremendous need for targeted focal therapies that are relatively easy to deliver and can prolong the quality of life for patients with intermediate risk localized prostate cancer. Sexual dysfunction, urinary incontinence, and rectal toxicities are all side effects associated with radical treatment options and can have tremendous negative impacts on a quality of life for these men.

Our goal in developing topsalysin is to create a safe alternative to delay or even eliminate the need for more radical therapies for the treatment of intermediate risk localized prostate and we are pleased that the improvements we made to this trial definitely improve on the Phase 2a results providing a greater proportion of patients experiencing treatment successful treatment of their targeted lesion.

At this time, I'm happy to turn the call back to the operator to open the line for questions. Operator?

Operator

(Operator instructions).

Our first question comes from Chris Raymond with Piper Jaffray, your line is now open.

Chris Raymond ***Piper Jaffray - Analyst***

Hey, guys. Thanks for the call and for letting me ask a question here.

So, just curious on this one patient death on second dose, I know it's early days but can you provide any color as to the cause of it? Is it some extenuating circumstances and then maybe can you walk us through the sequence of how we might find out more about the disposition of this and the FDA gets a chance to review it, et cetera? It'd be great. Thanks.

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

Okay. So, I'll take a first approach of that question.

Can I, first of all, just say that we have only recently been notified of the death and the event is under active investigation at this time. And i do not have anything definitive that I can share with you.

So, as soon as we do, then obviously, that will be communicated. However, we have followed all of the appropriate regulatory channels. We have informed all the regulators involved in the study and the ethics committees as well as all the investigators.

So, this is going through all the appropriate channels and as a precaution, we stopped further second administration dosing in this study. And I think that's really all I can say at this time.

Chris Raymond ***Piper Jaffray - Analyst***

Okay. Great. Thank you.

Operator

Our next question comes from Joe Pantginis with H.C. Wainwright, your line is now open.

Joe Pantginis ***H.C. Wainwright - Analyst***

Hey, guys. Good morning and thanks for taking the question and sorry to hear about the patient as well.

So, maybe just a little bit on the last question. I know you can't disclose -- or you don't have anything to disclose just yet. Do you have a wish as to what might be the latest you'd look to provide some information on this patient?

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

I really do not want to speculate on that because whatever I did speculate, I can guarantee it probably would not be the case, unfortunately.

All I can say is everybody's actively working together to get to this and understand this event as quickly as we possibly can. And everybody's working hard to achieve that.

Joe Pantginis ***H.C. Wainwright - Analyst***

Understood. Thanks. And then if I could just switch t the data, if you don't mind. Clearly, I believe the data were impressive especially after the single administration here.

So, maybe two questions for both Allison and Dr. Ahmed. First, are you pleased as you've talked to the centers regarding the uniformity of the procedure and the delivery?

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

So, I'll start and I'll ask Dr. Ahmed to comment.

So, I think as you would expect at this stage of development, yes, we were pleased but we could transfer this from just the hands of Dr. Ahmed here. The sites we chose were all experienced in doing targeted biopsies.

However, there are always learnings as you go into multiple centers that we would take forward. And one of those, I think, we would all agree that the site were all used to doing their targeted biopsies with their own registration software to marry those MRI images with ultrasound images. However, in this study we used a single approach with the SmartTarget elastic registration software.

And going forward, what we would do is allow the physicians to use whatever registration software they would use typically to do their targeted biopsies. That's where they have the expertise and that's one of the learnings, I think, I could say we would take forward from this small study.

Hashim Ahmed ***Imperial College College Healthcare NHS Trust - Chair of Urology and Consultant Urological Surgeon***

Hi. So, yes, I was personally very pleased with the results. I think we are seeing the benefit of learning from our pilot study which showed that we needed to work on the intervention in order to diffuse the drug through the tumor at a slower rate and we needed to standardize that across multiple users.

And being able to do that across eight centers across two continents, across many users. I think we should be -- I personally am very pleased with those results that we -- we have achieved as a result of learning from that early proof-of-concept study.

And just as Allison have said, I think we've learned there are a few more things that we can do with the intervention like allowing the local user to use an image fusion software system that they are most comfortable with and that they have most experience within and have used, it's probably something that pragmatically we should do as the use of image fusion software to carry out targeted biopsies is growing at a considerable rate with level one and now in the New England Journal of Medicine showing that MRI before biopsies absolutely the way to go.

So, I think we're going to get more and more experienced users who are able to do targeted biopsies, and therefore, we will have a large cadre of urologists that are able to do the injection of topsalysin when we eventually to the pivotal study.

Joe Pantginis ***H.C. Wainwright - Analyst***

Great. Thank you very much.

Operator

Our next question comes from Jason McCarthy with Maxim Group. Your line is now open.

Jason McCarthy ***Maxim Group - Analyst***

Hi, all. Thanks for taking the questions and to iterate Joe's sentiments, sorry about the patient passing. Could you take us back to the preclinical data. Were there any repeat administrations in those studies that would suggest that there could have been some type of adverse immune reaction on a repeat dosing?

I know you can't comment specifically about the patient but maybe you can take us back through some of the prior data and I know that the drug has been used in over 400 people, single dose. But , you know, back of those earlier studies in animals, was there anything that which would be suggestive of an immune response?

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

Yes. That's a very important question and we definitely address that before embarking on this particular study. There was a repeat dosing study in monkeys that we conducted before this where we saw no safety concerns and no impact on the ability of a second dose to ablate the prostate of the monkey.

And the monkey is probably our best model and that it has an encapsulated prostate and it also has enzymatically active PSA in the prostate. So, we saw no signs from the preclinical work and it is too soon to speculate on what may have happened here with this particular patient. It is recent and we are still actively investigating and that I really don't want to speculate too soon.

Jason McCarthy ***Maxim Group - Analyst***

Okay. And just one follow-up to that. Given that it was the only tumor to treat, could we assume that this was the last treated or is this earlier on and you're just -- you're just finding out about it now?

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

So, this was absolutely the last patient to be treated with the second dose.

Jason McCarthy ***Maxim Group - Analyst***

Okay.

Thank you very much. And also, just one on to go through the data, you know, the 29% is great and it's an improvement over -- over the prior study. But like in other cancer studies, could you consider even the partial responses, you know, you're going to go on to a second dose but, you know, that way did you include those in your overall response rate as upwards of 60% -- I'm doing that math right in my head.

Do you think about it that way or could it be reported that way?

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

I'll let Dr. Ahmed comment but -- so, this particular study, we set ourselves the goal of looking at clinical response as the primary efficacy outcome and that was taking a patient on histology of this treated lesion or the review of the biopsy data of the treated lesion.

We wanted to see even no tumor present or that that we had reduced that tumor to now being considered clinically insignificant. But I'll let Dr. Ahmed elaborate a little further.

Hashim Ahmed ***Imperial College College Healthcare NHS Trust - Chair of Urology and Consultant Urological Surgeon***

So, I think we have to stick by whatever any priority rules we had for defining a clinical response in the protocol. And yes, there were other men who had a partial response but I think in those men, they still had histological evidence of clinically significant cancer that in a clinical setting, of most physicians would want to then carry out further treatment on and that usually is radical therapy.

But I think what's encouraging about the 30% is that it's a good response in my mind because these 30% of men would otherwise require radical therapies and those radical therapies carry genitourinary toxicity and if you translate that across the tens of thousands of men who have surgery and radiotherapy. Currently, that's a big population of men, 30%, even if we remained at that 30% in a [perfect world] study, that's a considerable proportion men that would be able to avoid radical therapy and the impact on erections and continence as well as rectal toxicity from radiotherapy that they would be able to avoid.

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

And there is another aspect of the part. So, that's what we set a priority for our study. The partial responders, I think, also tell us that yes, they may still have a clinically significant lesion present that would warrant the treatment; however, it's telling us that our physicians can actually target that lesion and the topsalysin can ablate some of that targeted lesion but we may not have gotten enough of the drug to the lesion that we're targeting or we may need a little bit more volume to help us get to that whole tumor.

So, that's an important learning. So, those partial responders help us learn both in terms of delivery and the optimal way to deliver in dose.

Jason McCarthy ***Maxim Group - Analyst***

Great. Thank you very much for taking the questions.

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

Thank you.

And our next question comes from Matthew Cross with Jones Trading. Your line is now open.

Matthew Cross ***Jones Trading - Analyst***

Hey, guys. Good morning and thanks for taking my questions. So, for the single administration, I know you've reported patients are continuing this drug or essentially clean safety profiles, so I was wondering if you could comment on what safety looks like so far from these other 10 patients that have received the second administration?

Is there any kind of trend there that could offer an explanation for this single patient death or is it, potentially, a more of a standalone event that may not be drug related?

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

So, I think it's fair to say that. Yes. And I think we mentioned in the press release that the independent data monitoring committee for the study did meet in early May and review the safety data on all 38 patiens that had the single dose as well as the first seven patients that had received a second dose. And there were no untoward findings in their review following review of those patients.

And that's really all I can comment on at this time. Yes, we are reviewing and actively reviewing all of those safety data post the second dose.

Matthew Cross ***Jones Trading - Analyst***

Got it. Okay. That's helpful and I think --

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

Okay. But there was nothing that we saw following the first seven patients following the IDMC review of those patient's data. Okay?

Matthew Cross ***Jones Trading - Analyst***

Got it. No, I think that makes sense and is supportive of what the future work that may be needed to get to the bottom of this.

I also wanted to ask about the one case that resulted in TURP. And the circumstance around that that patient, was it deemed to be to be drug related or in any way related to, more of a like a response to topsalysin or what was the rationale for the urinary retention and required TURP?

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

So, the patient that had a moderate urinary retention that went on to receive a TURP to resolve that was -- could either be due to the actual procedure. We're actually injecting into the prostate that is at risk of going into potential urinary retention.

I do believe that this patient also has BPH as well associated. So, maybe not so much drug but it can't be ruled out but more to the procedure of undergoing an intraprostatic injection. If that makes sense.

And I'll ask Dr. Ahmed to comment.

Hashim Ahmed ***Imperial College College Healthcare NHS Trust - Chair of Urology and Consultant Urological Surgeon***

Just to add to that, there is a small risk of triggering urinary retention which then doesn't resolve and require something like a TURP or a laser procedure even after a prostate biopsy, so very low incidence of it. But I think a man who has a BPH and is at risk of urinary retention, any kind of intervention can flip them into urinary retention that then doesn't resolve and obviously with one case of this very difficult for us to find a pattern. But it can happen with just a simple prostate biopsy, in my experience. It's a very low incidence but it can (inaudible).

Matthew Cross ***Jones Trading - Analyst***

Okay. Makes sense and appreciate the clarity. And if I can just squeeze in one more.

Speaking hypothetically, if it was possible that something didn't go exactly as planned with the delivery itself, per your recent comments of topsalysin, is there any kind of mechanistic reason why topsalysin which can be active outside of the high PSA prostate tumor environment?

So, we know that to activate topsalysin, you need enzymatically active PSA. And the enzymatically active PSA that's in -- that the PSA [we hope] that is in circulation is not enzymatically active and we're also injecting into an encapsulated prostate. So, that's all I could really say at this point.

Does that help?

Matthew Cross ***Jones Trading - Analyst***

Great. Yes. No, absolutely. Thank you so much for addressing my questions.

Allison Hulme ***Sophiris Bio - COO and Head of Research and Development***

Thank you.

Matthew Cross ***Jones Trading - Analyst***

Appreciate it.

Operator

And I'm showing no further questions. I'd like to turn the call back over for closing remarks.

Randall Woods *Sophiris Bio - President and CEO*

Thank you, Operator.

I would like to express my thanks to Dr. Ahmed for joining us today and for continuing to support topsalysin and Sophiris. And I want to say a special thank you to all of patients and physicians who participated in this Phase 2b study of topsalysin.

On behalf of the entire Sophiris team, we appreciate you joining this on this call today and we look forward to providing you with updates as they become available. Thank you.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This does include the program. You may now disconnect. Everyone have a great day.

END