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SPHS - Sophiris Bio Inc Review of Topsalysin Clinical Data Conference Call

EVENT DATE/TIME: JANUARY 28, 2016 / 11:00AM PST

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PRESENTATION

Operator

Good day ladies and gentlemen and welcome to the Sophiris Investor Conference Call.

At this time, all participants are in a listen-only mode. Later, we will conduct a question and answer session and instructions will follow at that time.

(Operator Instructions)

As a reminder, this conference call is being recorded.

I would now like to introduce your host for today's conference, Mr. Peter Slover. Sir, you may begin.

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

Thank you Lynn. Thank you for joining us on today's call.

On the call today, we intend to discuss the preliminary results from our Phase 2a study of topsalysin in men with localized prostate cancer. Details of which were announced earlier today in a Press Release now available on our website at www.sophiris.com.

We also intend to discuss the results of our previously announced Phase 3 study of topsalysin as a treatment for the symptoms of BPH, also referred to as enlarged prostate.

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 is 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 UK; as well as Dr. Marc Gittelman, a board certified urologist who is both an investigator and the central reader for the uroflow assessment in the Phase 3 PLUS-1 BPH study and is the Director of the South Florida Medical Research.

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 treatment of localized prostate cancer or symptoms of BPH constitute forward-looking statements that are subject to risks and uncertainties relating to Sophiris's 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's filings with the US Securities Commission, which can be assessed 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 then Dr. Hulme and Dr. Gittelman will review the results of the BPH Phase 3 study. Randy will then provide closing remarks on our strategy for moving the company forward.

I will now turn the call over to Randy. Randy?

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

Thank you Peter. Today is an especially important day for Sophiris given the encouraging data that we have just reported in the Press Release issued this morning. Researchers have observed in our Phase 2a proof of concept study that biological activity was seen in four out of seven, one of which was a complete tumor ablation. Allison and Dr. Ahmed will explain the significance of this later in the call.

This data in prostate cancer comes on the heels of a positive Phase 3 study of topsalysin in BPH announced last November, which successfully met its primary endpoint. Supported by these clinical results, we firmly believe that the elegant, highly targeted and specific mechanism of action of topsalysin is validated by both the efficacy and the safety profile that we are observing in both of these indications. These data also increase our confidence in advancing topsalysin into a second very important indication, the focal treatment of localized prostate cancer in addition to the BPH indication.

Sophiris now has positive clinical data highlighting therapeutic activity in two separate indications. Importantly, topsalysin represents the potential to fill a major treatment void in two separate urological diseases. Similar to BPH where there are few treatment options between oral medications and the more invasive surgical procedures, men with localized prostate cancer have few focal therapy treatment options between active surveillance and radical therapies.

We are very enthusiastic today to share with you the highlights from our two clinical trial programs, which will be reviewed by Dr. Allison Hulme and two clinical experts, doctors Ahmed and Gittelman who have been intimately involved in the development of topsalysin. At this time, I'll now turn the call over to Allison.

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

Thank you Randy. I would like to first of all focus our attention on the Press Release we issued today on the localized prostate cancer indication. We will shift to the BPH Program later in the call.

As a way of a little background on topsalysin, topsalysin was initially designed and conceived to be a treatment for prostate cancer. However, at that time, almost 10 years ago, the regulatory path to approval in prostate cancer was not at all well defined.

Traditional cancer survival studies would have been impractical not only in terms of patient numbers, but also the duration of the study that would have been needed. Therefore, we chose to initially focus the development of topsalysin for the treatment of patients with BPH where the regulatory precedence had already been established with the approval of the oral drugs.

Until recently, men with clinically significant, but localized prostate cancer that has not progressed outside the confines of the prostate have two choices of treatments, which are at the extremes of care.

One, they may choose to enter active surveillance in which they receive no treatment but undergo periodic PSA testing and then as indicated periodic prostate biopsies. Or two, they may decide to undergo radiation of their prostate or even complete removal of the prostate in the form of a prostatectomy, often with substantial and permanent quality of life side effects such as urinary incontinence, erectile dysfunction and rectal toxicity.

More recently, an alternative approach is being offered to some patients the option of focally treating localized disease, which is actually consistent with current treatments for solid tumors such as breast and liver cancers where the goal is to remove the tumor and preserve as much of the organ as possible. Increasing use of

multi-parametric MRI along with advances in software that maps these images to real-time ultrasound images now enables physicians to more accurately locate tumors within the prostate when they obtain the biopsies. This increases the accuracy by which men with clinically significant lesions are identified.

The breakthrough for us is the ability to inject an enzymatically-activated ablative agent such as topsalysin directly into the identified tumor using this imaging technology. Topsalysin has been engineered to be activated only by enzymatically-active PSA, which is only found in the prostate tissue. We believe that with these technical and medical advances, topsalysin has the potential to become a focal targeted therapy for the ablation of localized prostate cancer while avoiding many of the complications and side effects that we just discussed associated with radical treatments that are aimed at the entire prostate.

In May of last year, we initiated a Phase 2a proof of concept open-label trial in patients with localized prostate cancer at a single center in the United Kingdom, the University College London with two world-renowned experts in the focal treatments of localized disease, these being Drs. Mark Emberton and Hashim Ahmed.

As mentioned earlier in the call, we are delighted to have Dr. Ahmed, the principal investigator for the proof of concept study on the call with us today. Dr. Ahmed participated on FDA and other regulatory health authority panels advising on how best to move the field of focal treatment of localized prostate cancer forward.

Dr. Ahmed has personally administered topsalysin to all of the 18 patients that have been treated in our proof of concept study and therefore is extremely well qualified to share with us his experience with the study and his thoughts regarding the potential of topsalysin to focally treat patients with localized disease. 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 Hospital - MRC Clinician Scientist, Honorary Consultant Urological Surgeon***

Thank you Allison. It's a pleasure to be here today. In the study, we entered patients who had an MRI visible lesion, which was confirmed to be clinically significant by targeted biopsies and that's warranted treatment for that man.

The previously obtained multi-parametric MRI images of clinically significant lesions have been mapped to real-time three-dimensional ultrasound images to facilitate the injection of topsalysin into and around pre-identified lesion. The primary objective of the study is to assess the safety and tolerability of the administration of a 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 3 BPH study.

We have now treated 18 patients with clinically significant prostate cancer with various doses of topsalysin, all greater than what was given in the BPH Program. No serious adverse events have been observed and no new safety signals have been 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. A review of the biopsy data from the first seven patients to complete the study to date showed that four patients had a response to treatment. One of those patients experienced complete ablation of the tumor where no evidence of the treated tumor remained on a targeted biopsy at six months.

Three patients experienced a reduction in the maximum cancer core lengths or a reduction in the Gleason grade pattern. Three patients had no response to treatment with topsalysin. These results are encouraging.

It appears that topsalysin does have the potential to ablate cancer cells and appears to be well tolerated with little in the way of side effects. This presents a potential opportunity to treat patients who have clinically significant localized prostate cancer with topsalysin, ablate pre-identified lesions and downgrade the patient to nonsignificant cancer. This is actually clinically meaningful as it may help men either avoid or delay the need for radical therapies.

We look forward to reviewing the data from the remaining 11 patients, which should provide us with the valuable experience on how we might optimize both the delivery and the dose of topsalysin based on lesion size for future studies. I'd now like to turn the call back over to Allison.

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

Thank you Dr. Ahmed and I really would like to take this opportunity on behalf of Sophiris and myself to thank both yourself and the entire team at University College London and in particular all the patients that have participated in the study. We really look forward to being able to review the complete data set on all 18 patients by the end of the second quarter.

I would now like to turn our attention to the BPH Program and the review of the results from our Phase 3 study, which we referred to as the PLUS-1 study, which successfully met its primary endpoint as we reported last November.

The PLUS-1 study is the first of two planned Phase 3 studies that would be required for registration and eventual approval of topsalysin for the treatment of lower urinary tract symptoms of BPH. The PLUS-1 study was an international multi-center, randomized, double-blind and vehicle-controlled trial of 479 patients. The patients were enrolled across 75 centers that were located in the United States, Canada, Russia, Ukraine, Australia and New Zealand.

The study was designed to assess the efficacy and safety of a single transrectal intraprostatic administration of topsalysin. Patients were randomized in a one to one ratio meaning equally to either topsalysin or vehicle-only injection. The vehicle was a volume of saline that was injected into the transition zone of the prostate equal to 20% of the size of the patient's total prostate, so it was not a sham injection.

In this study, the treatment was individualized to inject the same amount of drug irrespective of the size of the prostate. Following the single administration of study drug, patients were monitored for a year. It is a privilege to have Dr. Gittelman on the call to review the results of the study.

Dr. Gittelman was a principal investigator in the study. In addition, he was the central reader for the uroflow or Qmax. Dr. Gittelman has also been involved in the clinical trials of all the approved oral medications for BPH as well as a trial of a minimally invasive surgical technique or MIST.

Also worth noting, he was an investigator in the clinical trials for two other intraprostatic injectables that were being evaluated by Allergan and Nymox so Dr. Gittelman is more than well qualified to share with us his thoughts on the key results from the PLUS-1 trial. Dr. Gittelman, the floor is yours.

Marc Gittelman - ***South Florida Medical Research - Director***

Thank you Allison. Good morning to our West Coast audience and good afternoon to our East Coast audience and those in between.

As reported in November, this study met the primary endpoint and showed that a single treatment with topsalysin resulted in statistically significant improvement in BPH symptoms and that symptom relief was sustained over at least a year period.

The primary endpoint was the IPSS total score change from baseline over 52 weeks. This was analyzed using repeated measures with no imputation of missing data per guidance from the FDA.

The IPSS of course is a compilation of seven questions that we ask our patients about hesitancy and frequency in urinary stream and nighttime waking. It's the -- It's the gold standard tool that we use in research so it really captures many of the symptoms these patients suffer from.

At 52 weeks, the observed overall improvement of 7.60 points in the topsalysin group was statistically significantly superior to the 6.58 point improvement in the vehicle group with the P-value of 0.043. So one may wonder why is the vehicle-only response so high? It's important to note that there is significant precedence for high vehicle response for intraprostatic vehicle injections and it's not at all unique to this particular trial. The same kind of response of the same magnitude actually was seen previously in clinical trials with two other prostate injectables.

As Allison told you, I participated in both of these trials and I'm speaking of course of Nymox's compound, NX-1207 and Allergan's Botox.

In the typical pharmaceutical trial, much of the placebo response can be described to be psychological improvement from receiving a therapy that patients perceive will help them —and granted some of that is present here. But for trials such as this using an injectable vehicle, we must take into account the mechanical effect of flushing the prostate with the large volume of liquid which undoubtedly disrupts the cellular architecture of the cells and the prostate.

When we, as urologists treating patients everyday with BPH see data of this magnitude, we're way more focused on the absolute magnitude of the peak IPSS improvement of 8.3 points from baseline and the overall improvement of 7.6 points over 52 weeks then we are in comparing statistical changes versus the vehicle. Of course meeting statistical significance with topsalysin versus vehicle is important and the numbers bear that out. But as clinicians, we're interested in the magnitude of the benefit.

That our patients actually experience. That is the absolute change of their feeling that's clinically meaningful to them and to us. So, for patients that means less hesitancy, improved stream, less urgency, less night-time waking and their perceived quality of life improvements which we will explore in a moment.

And by the way, of course this trial is not designed to compare with alpha-blockers. But if you were to look at the literature and hopefully you have for the alpha-blockers and the five 5-alpha reductase inhibitors you would find topsalysin data far superior to the IPSS improvements found in those clinical trials.

So, now, let's switch over just a bit and talk about preservation of the symptom response in these patients. In the secondary analysis of efficacy of IPSS using ANCOVA model in standard approach of last observation carried forth to impute missing data, the improvement in IPSS for topsalysin was well-sustained just with one single administration.

While improvements in IPSS were observed at the very first post-treatment assessment week six, the maximum effect was actually seen at week 18 when it was 8.31 points improved and importantly an 8.04 point improvement remained at week 52 representing an end of study preservation of 97% of the peak benefit.

Secondary efficacy endpoint results were supportive of the primary endpoint findings for example in the analysis of the max flow rate we call Q-max over 52 weeks showed overall improvement in the peak urine flow of 1.77 milliliters per second for topsalysin representing a statistical trend with a P-value of 0.055 narrowly missing statistical significance compared to vehicle group.

And while we are appropriately focused on the numbers, the patients are focused of course in their clinical improvement. We utilize two quality of life questionnaires that were part of the assessments. Patients in the topsalysin group had a better outcome than the patients who had received a vehicle injection, a difference that was statistically significant.

As an example on the zero to 6 point BPH specific quality of life questionnaire, patients who received topsalysin self-assessed an average improvement of 1.6 to 1.7 points over their baseline of 4.5 points.

And just as with the IPSS preservation, the improvement in quality of life was sustained from weeks 18 through week 52. The observed improvement in quality of life was statistically significantly superior to vehicle for every post baseline visit beginning at week 18 reaching a P-value of 0.004.

This suggests that they were effects of the drug that were not adequately captured by the IPSS and Q-max measurements. And those patients still significantly better after treatment with topsalysin versus those patients who had been randomized to vehicle only.

So, just for a moment, let's discuss the safety results. In this study, the safety profile for topsalysin continued to be favorable, as had been observed in each of the four previous clinical studies in BPH. The treatment was generally well-tolerated and no patient was withdrawn from the study or had their study drug injection altered because of an adverse event.

On average, the injection itself was completed in less than four minutes. This was actually recorded with the study data. This is an important and very attractive part of this therapy for us treating our patients on the frontline and trying to be as efficient as possible with our time and at the same time balancing how what we actually do impacts possibly for our patients, microwave therapy for example last 28 and a half minutes.

From a patient's perspective, the fact that there was no evidence of any treatment related sexual or cardiovascular side effects, further makes it an attractive option for them. Retrograde ejaculations are common adverse event for patients on alpha-blockers as are possible orthostatic changes, dizziness, lightheadedness, et cetera. So, these adverse events are not well-tolerated in the alpha-blockers and are probably part of the equation as to why nearly 50% of patients fall off their alpha-blocker therapy by three years.

So, in summary, topsalysin is a highly targeted treatment for prostate disease designed to be at least as efficacious as oral pharmaceuticals but less invasive than surgical interventions and without the sexual and cardiovascular side effects that maybe seen with the existing treatments.

The observed, sustained, and meaningful efficacy in the plus one study combined with the favorable safety profile makes topsalysin if approved for use a particularly compelling potential option for men suffering from BPH.

Topsalysin is the only single administration investigational treatment for BPH that has demonstrated a statistically significant improvement in symptoms of BPH in a phase three trial. So in closing, I would like to give some perspective on how topsalysin fits in the spectrum of how patients perceive their therapeutic option.

Getting patients to consider therapy even with an oral agent sometimes can be difficult often easier when they have a significant symptom, but moving to a minimally invasive therapy such as microwave is a huge leap for them not to mention considering interventions such as laser or TRP.

But patient's perception of an injection into the prostate is more easily comprehended, they had other injections in their life and many have already had prostate sonogram so the concept of a four minute procedure is very attractive to them when they think about the other therapies that we have in that spectrum. And finally topsalysin fits in its own new niche when we look at the spectrum of armamentarium for urologist.

Similarly prescribing meds for us is very easy but moving to the minimally invasive therapies more invasive and certainly more time consuming. Intra-prostatic injections are so familiar to us since we do this virtually every day of the week when we would administer local anesthesia for prostate biopsies. So, administering topsalysin would be very easy to adapt into our armamentarium as an easy and efficient way to administer an effective therapy. With that, I now like to turn the call back over to our colleagues at Sophiris.

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

Thank you Dr. Gittelman and thank you Dr. Ahmed for taking time out of your busy schedules to be with us today. With that backdrop provided on the call today, you can see the incredible momentum and opportunity created in the past few months that positions us for a transformational year in 2016. Topsalysin has demonstrated a statistically significant improvement in symptom score in a phase three study of men with BPH supporting further development in a second and final phase three study required for marketing approval with the FDA.

Topsalysin has now demonstrated promising therapeutic activity in four of the seven patients with localized prostate cancer expanding the breadth of our PRX302 program into a second indication beyond BPH and into an exciting new indication the focal treatment of localized prostate cancer. Data from both programs increases our confidence in the precise mechanism of action of the drug, demonstrates therapeutic activity in both indications and further validates the well-documented safety profile seen to date.

I'd like to share with you our strategy for 2016 now with this robust pipeline in urological diseases and significant opportunity ahead. Topsalysin has the potential to address the three million patients with BPH who are failing to achieve their goals with oral medications. Our medial advisors who have reviewed the data indicate that a once a year office based procedure will be a welcome option for those patients caught between the modest benefits of oral medications and the more invasive surgical procedures.

Further topsalysin's encouraging activity in localized prostate cancer opens up a new market for patients faced with a difficult decision of the treatment with radiation therapy or the complete surgical removal of their prostate. In both of these indications, we are potentially offering patients the alternative to expensive procedures that come with life-altering side effects. This would be a win for patients faced with difficult treatment decisions, for physicians with limited treatment options and for payers looking to temper cost of the care.

As we look ahead to our path for optimizing the value from these programs, we now have a number of strategic options at our disposal. And we sit in a much more enviable position than just a few months ago before data from each of these two programs was available. The next step for the BPH program is to conduct a second pivotal phase three registration study that would be very similar to the one we just successfully completed.

Regarding the program in localized prostate cancer, our plan is to advance into a dose and delivery confirmation study assuming the results of the next 11 patients are consistent with the current findings. This small study could be undertaken quickly and would enable us to optimize the delivery and dose of topsalysin to ablate targeted tumors prior to initiating a phase three potential registration study.

Our clinical investigators are enthusiastic about the data seen so far and excited to aggressively move this program forward in the clinic. As you can see, Sophiris has significantly strengthened its position in the development of novel therapies and treatments for urological diseases. We have promising data in two large indications and multiple pass for continuing to advance those programs into late stage clinical development.

In the midst of these exciting times at Sophiris, I would be remiss if I close this call without first thanking all the patients and physicians that have helped in the development of topsalysin to date. I would like to also thank our shareholders who had been extremely patient and supportive over this management team and who also have remained steadfast believers in the incredible potential of topsalysin.

Thank you very much for allowing us to share our story today. We believe 2016 will be our best year yet. This concludes our formal remarks.

I'll now turn the call back over to the operator.

QUESTION AND ANSWER

Operator

(Operator Instructions)

Our first question comes from the line of Jason McCarthy with Maxim. Your line is open.

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

Hi, guys congratulations. This is really, really exciting data even though it's early stage it's very suggestive that you do have something that's going to work in prostate cancer. You know, just a couple of questions. When you did the initial MRIs, what was the lesion size and how many lesions did these patients have?

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

So, we're going to ask Allison to respond to that for you.

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

Okay. So, I'll make an initial answer on that. But I think since we have Dr. Ahmed on the call we can ask him to contribute to that answer as well.

So, the lesion sizes do vary in terms of roughly from about I say 0.2 up to about 0.5 but what we were really looking for was looking for clinically significant lesions and so this protocol we defined that the lesion his maximum cancer core [length they sit] with Gleason 6 have to be greater than 3 millimeters and if it was a Gleason 7, we take any maximum cancer core length up to 10 millimeters. We didn't want the lesions to be too large for this initial proof-of-concept study. Hash would you like to comment anymore on that?

Hashim Ahmed - ***University College Hospital - MRC Clinician Scientist, Honorary Consultant Urological Surgeon***

Yes. That's a great question, so we choose men that needed treatment. So, in any healthcare setting, these men would have clinically significant disease which may be classified overall as low risk but they would have a lesion on MRI which met some minimum criteria on a targeted biopsy or they would have intermediate risk disease which again was either intermediate through a significant amount of cancer on the targeted biopsy or Gleason grade.

So these men needed treatment, we wanted to because this was a proof-of-concept study ensure that there were no other lesions so these men have a very accurate multi-parametric MRI reported by expert radiologists and then they have targeted biopsies of that lesion to make sure that was the only lesion that was present.

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

Great. I know it's early -- it's a six-month readout on the biopsy, the higher dose 5 microgram per gram of prostate. Will you follow up with any of these patients longer maybe 12 months out, 18 months out trying to gauge the durability of the therapy beyond six months, especially from the patient that was completely ablated?

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

Sorry, and I'll just jump in -- sorry, the proof-of-concept study will only follow them after six months but Hash I think you can speak to the fact that these are patients in your clinical practice and you will be continuing to follow them so that we can determine the next steps with those patients, so we'll have access to that, Hash?

Hashim Ahmed - ***University College Hospital - MRC Clinician Scientist, Honorary Consultant Urological Surgeon***

Yes. So, we'll -- yes -- so, again a great question there. We are committed to following up every single patient that we treat in our academic tertiary referral center in focal therapy for the rest of their life so we will be able to see what happens to these men on a regular basis with PSA follow-up and imaging and biopsy follow-up if necessary then we are committed to that -- the trial itself is limited to six months post treatment follow-up but we are in our clinical practice committed to following them up long-term and we'll be very opened and transparent about that longer term follow-up for all the patients under our care.

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

Okay, great, thanks guys, congratulations again. It sounds like things are going really well.

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

Thank you.

Hashim Ahmed - ***University College Hospital - MRC Clinician Scientist, Honorary Consultant Urological Surgeon***

Thank you.

Operator

Thank you. Our next question comes from the line of Doug Loe with Euro Pacific. Your line is open.

Douglas Loe - ***Euro Pacific Canada - Analyst***

Yes, thank you very much and good morning, actually good afternoon here and congratulations on the new prostate cancer data, very impressive. A couple of questions one focusing on new data and one on the BPH marker opportunity, if I may. Starting with the prostate cancer data, certainly impressive to with [four] seven patients, so the substantial tumor response, always interested in just how medical markets sort of stratified themselves among responders and not responders.

So, I'll be interested from your clinical collaborators on what their medical intuition is telling them about what the reasons might have been for the patients who didn't respond as well to topsalysin therapies. You know, if they're like -- the lesion PSA levels or [pursuing protease] activity of PSA in the lesions, could have been an issue or perhaps some geometric considerations for, where the lesions are actually penetrating with the injection. I mean I'm just kind of spitballing just because -- I'm kind of wondering if you have any early insights as to how responsive patients could be stratified based on this early data.

And then, I'll just ask a BPH question here and then listen to your responses. Just based on the commentary on plus one data which was quite positive, sharing our point of view in the data as well, it certainly sounds to me as though you might see the topsalysin as actually being more comprehensively applicable to BPH market than -- than actually our model assumes where we just -- we assumed primarily that topsalysin would sort of compete for market shares in the TRP market.

It certainly sounds to me like you think it might be more comprehensively applied perhaps even to first line therapy either pre or concurrent to alpha blockers or 5-alpha reductase inhibitors being used. So just maybe just some early insights into how you think the topsalysin would be infused into existing standard of care based on your clinical experience and look for the insights on both of those questions. Thank you.

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

Okay, thank you Doug. This is Allison. I'm just going to start off on the prostate cancer question. First of all and do we have any idea as to why three patients did not respond and I think it's safe to say -- and I'll ask Hash to comment afterwards but it's really a proof of concept where we have various dosing as to the 5 microgram per gram of prostate that we've been dosing.

So not every patient got that dose, depending on the size of the tumor and the size of their prostate, we have been looking at different doses, so it is very early days. It's only seven patients. We will continue to evaluate what those three patients were given and we'll also look at all of the data.

We do need more data from the remaining 11 patients to be able to be definitive but we do believe that we'll be down to not only how we deliver the drug into and around that tumor but also the actual dose of drug going into the tumor itself. So, these two patients -- the first seven patients are giving us some good data on that.

The other 11 is consistent with that. We'll help then design how to optimize but the delivery of the drug into the tumor as well as the dose based on the size of the tumor itself. So, it's just early days and I say we still got quite a bit of work to do on optimizing delivery and the dose but I'd like to invite Hash to comment on that.

Hashim Ahmed - ***University College Hospital - MRC Clinician Scientist, Honorary Consultant Urological Surgeon***

So I agree, again a good question. So, we need to learn from the study and that really to me is what a proof of concept study is about. We want to see if there's a signal, a biological signal. We think there is potential for -- we know there's a biological signal from these first seven patients but we need to see whether that's consistent in the remaining 11 patients.

And I think it's going to be about the delivery and the doses as well but what we will do is we will intuitively learned from these 18 patients that we treated within the trial and then evaluate those results and look at how we can change the intervention, the delivery and the dose going forward.

Douglas Loe - ***Euro Pacific Canada - Analyst***

That's great feedback, thank you.

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

Okay.

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

This is Randy I think with the ...

Marc Gittelman - ***South Florida Medical Research - Director***

Go ahead Randy.

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

Go ahead -- I was just going to say that with regard to the BPH and where we'll see that being positioned, I'd be interested in Dr. Gittelman's comments as well but I think where we see this, in the United States, you know Doug, there's about 3.2 million men who received treatment for the BPH symptoms. And 3 million of those 3.2 million men are on some kind of oral medication like an alpha blocker or 5ARI.

And so what we see happening is that in -- within about two to three years, about 60% of those patients do discontinue their oral therapy. And you know when they go back to the physician and they talked about what the next step may potentially be and they talked about these more invasive surgical techniques, most of these men really call time out and really don't want to take that leap to the more invasive surgical techniques.

And so it's really right after those men have discontinued their oral medications that we see our drug being used with those patients before they would go unto some of the more invasive surgical techniques. I'm sure Dr. Gittelman would have some comments in where he sees that as well.

Marc Gittelman - ***South Florida Medical Research - Director***

Yes, very interesting question Doug because it gets into the psyches of really what our patients are thinking. I think that move -- when they move from a pharmacotherapy to actually call doing something, there are a couple of things that are going on for that patient.

Either number one, they just are not satisfied with their therapy. They're taking medicines, sometimes once a day, sometimes we double dose with tamsulosin, sometimes on combination therapy, and they don't perceive enough value. They're still waking up at night, they're still bothered and they're looking for answers.

There are people who sort of just don't want to take medications for the rest of - and you will be surprised that they're sort of out there, sort of like why somebody might do a LASIK procedure for their eyes instead of wearing glasses for the next 10 years, and then there are times they're sort of physiologically in trouble. They might getting recurring infections or their residuals are too high and we sort of push them along.

But in their mind, the word really is "leap" from pharmacotherapy to quote, doing something and even though we called them minimally invasive therapies, they really are compared to we're doing GreenLight Laser or we're doing a the old fashioned TUR which we almost never do, but it's still doing something. They want to know about the procedure. There's a lot of anxiety, etc.

The concept to me, for the patient and to kind of educate them in terms of what they would be doing for this procedure, this is a much easier thing for them to see the light, so to speak. We're going to be doing an injection into your prostate under ultrasound guidance.

Many of them may have had ultrasounds already either for sizing or they may have even biopsies already which they've already sustained injections into their prostate. So that -- that leap, if you will, is more like a "hop" than it is a leap for them.

So, I think patient-wise, this will be -- to tell them it's a four-minute procedure, we're going to give injections. I think that will be more easily accepted by patients. So to me, this is not part of minimally invasive therapies. This is its own new niche.

That's from the patient side, from the doctor side of things, it's going to be very interesting because just as our philosophy right now, we never take a patient for surgery whom we've haven't done a minimally invasive therapy on. I mean -- at least we got a [big no] of but the point is that we really -- we see that as that's the next step.

And I think that because this is so easy, a lot of urologists, again, efficiency of their time is incredibly important. That moving to something that's as easy as a four-minute procedure that has -- as good a result as we're seeing here with the IPSS team, is going to be easily adopted by the urologist.

Douglas Loe - ***Euro Pacific Canada - Analyst***

Yes, I know, that's great. No just to -- just to kind of cap it off from my perspective I mean, you know, surveying your commentary and side effect profile coupled with a negative IPS responsiveness, it just -- it just looks to me like a nice alternative to pharmacologic therapy and that's why I was interested in your feedback there. Thanks very much guys.

Marc Gittelman - ***South Florida Medical Research - Director***

Sure, you know I don't want to take up too much on this question but the adverse events that people experienced, retrograde ejaculation is not a small thing. I mean it depends on the patient but the date is probably relatively underrated for -- even for the alpha blockers, alfuzosin and Rapaflo is I think 28% was in their clinical trials.

And depending on the data, you look for tamsulosins from 14% to 28% and -- but I can tell you it's a lot -- it's a lot higher in the real world and I will -- we'll leave it at that.

Douglas Loe - ***Euro Pacific Canada - Analyst***

Got it, thanks very much, thanks Randy.

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

Thank you.

Operator

Our next -- our next question comes from the line of [Boris Peaker] with Cowen & Company. Your line is open.

Boris Peaker - ***Cohen & Company - Analyst***

Great, thanks, congratulations on the encouraging data. I guess I just wanted to ask ...

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

Thanks Boris.

Boris Peaker - ***Cohen & Company - Analyst***

-- specifically in terms of the procedural element of delivering the drug. So, I mean what special equipment would the physician need to do this MRI with ultrasound imaging, do they need special training? I mean are urologists using this technology or comfortable using this or is this something new in their practice, could you just elaborate on that?

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

Right, I'll start from that and then again, I'll hand that over to Dr. Ahmed because this is a common question that comes up with the use of focal treatment for localized prostate cancer. I think in Europe it's a little bit more commonplace than it probably is in the US

We are, I would say, the cusp of the use of MRI for targeted biopsies, gaining appeal. It's not fully established in the US yet but the idea of sending a patient for multiparametric MRI is gaining acceptance. So large urological practices are doing that and then they purchased fusion software which actually helps map those MRI images that they obtained previously on their patient's prostate.

And then they can map to the live ultrasound images that they're seeing when they have the patient on the table in front of them. It doesn't take a lot of training for them to do that. I think part of several training courses at some of the urology conferences where that happens but I think it's probably better if you hear from Dr. Ahmed as well.

Hashim Ahmed - ***University College Hospital - MRC Clinician Scientist, Honorary Consultant Urological Surgeon***

Thanks Allison, so I think what we have spoken about today is the revolution that's happening in prostate cancer diagnostics and only two years ago very few centers were using multiparametric MRI and targeted biopsies. And over the last one to two years, the number of centers doing an MRI before biopsy, doing targeted biopsies has grown substantially, and it's changing the entire pathway.

It means we can accurately diagnose men. We can accurately reassure men that they don't have clinically significant cancer and once you have a lesion on an MRI and the rest of the prostate on the MRI looks clear, then they paradigm shift to focal therapy to treat just the lesion itself becomes that much easier.

So I think and I use the word, knowing what the consequences are, but it seems we revolution in the way we are diagnosing and subsequently treating prostate cancer. Yes, there are going to be training needs, so we need a whole cadre of experts, uroradiologists and our colleagues in radiology are now stretching up training programs for that.

And then the subsequent training aspect and equipment aspect will be targeted biopsies, but as a result of papers in [jammer] and a number of systematic review showing that targeted biopsies are better than how we are currently diagnose a prostate cancer, I think that change over the next one to two years will be inevitable.

And then the key skills required for targeting a lesion with injectables are -- should be there. We will obviously within trial quality manage that and quality control that but the key attributes and skills in good centers should already be there by the change in the diagnostic paradigm.

Boris Peaker - *Cohen & Company - Analyst*

Got you, okay, and I'm just curious in terms of procedural reimbursement, I mean obviously oftentimes that drives physician's decisions, you know, if we compare it to some of the other alternatives. I mean where do you anticipate this to stand from incentive to doctor to use?

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

I think it's still really too early to tell. This is such a sort of new technology, new therapy and new approach. So, I think we'll obviously we'll be doing some more work on that but I think it's just a little too early to tell at this point.

Boris Peaker - *Cohen & Company - Analyst*

Got you, one last question, could you just highlight the key catalyst, I mean specifically relating to when we anticipate to start of the second Phase 3 BPH study and also maybe any future studies in prostate cancer?

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

Yes, so as we said, we definitely will need to do a second Phase 3 clinical trial for the BPH indication and so we're really right now looking at what the alternatives would be to move that -- that trial forward. And likewise with the, proof of concept prostate cancer study, I think the next step there is a small study that we made reference to maybe in the call that would help us better define the dosing and volume of the drug needed to hopefully achieve an even better result than what we've seen already.

And so beyond that, then I think we could -- assuming we continue to see good results, we can maybe then move into a Phase 3 or even registration study for the prostate cancer indication. And so I think that right now what we're doing is just really evaluating the strategic options we have to advance both of those programs forward. And I think with the robust clinical data that we have from both programs currently, I think we're in a much better and stronger position than we were even just a few months ago and have more options available to us, so more on that later.

Boris Peaker - *Cohen & Company - Analyst*

Okay, great, well thank you very much for taking my questions and again congratulations on the data.

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

Thank you.

Hashim Ahmed - *University College Hospital - MRC Clinician Scientist, Honorary Consultant Urological Surgeon*

Thank you.

Marc Gittelman - *South Florida Medical Research - Director*

Thank you.

Operator

Thank you and I would now like to turn the call back to management for closing remarks.

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

Yes, so this is Randy Woods. I just like to thank everyone for joining us on the call today. Obviously, we're very excited about these continued good results with topsalysin and we actually look forward to providing an update for all of you towards the middle of this year. So, 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. Everyone have a wonderful day.