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

Topsalysin successfully ablated tumor cells in patients with clinically significant localized disease
Investor webcast scheduled for today at 2:00 p.m. Pacific Time

SAN DIEGO and VANCOUVER, British Columbia, June 9, 2016 /PRNewswire/ -- Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), a biopharmaceutical company developing PRX302 (topsalysin) for the treatment of urological diseases, today announced the biopsy results from all 18 patients enrolled in the Phase 2a proof of concept study of topsalysin in localized prostate cancer. The one-time administration of topsalysin was well tolerated with no serious adverse events and no new safety signals being reported. Topsalysin demonstrated an ability to ablate tumor cells in 50 percent of patients (9/18 patients) six months after treatment in a patient population with pre-identified, clinically significant prostate cancer. The results support advancing topsalysin into a Phase 2 study to confirm dose and optimize delivery.

"These promising early results open up the possibility of treating early prostate cancer by the simple administration of an injection into the prostate - something that could be done in an office setting," according to Dr. Mark Emberton, Investigator, Dean, Faculty of Medical Sciences, University College London and Honorary Consultant Urologist at University College London Hospital NHS Foundation Trust.

All 18 patients enrolled completed the study. Biopsy data at six months following treatment showed that:

- Two men experienced complete ablation of their targeted tumor with no evidence of any tumor remaining at 6 months;
- Seven men experienced a partial response, defined as either a reduction in the maximum cancer core length or a reduction in Gleason pattern;
- Nine patients had no response to treatment.

"It was impressive to observe complete tumor ablations in this proof of concept study. We have demonstrated that topsalysin can safely ablate prostate tumor cells, so these responses increase our confidence that topsalysin could obviate or prolong the time to the need for radical therapy in this patient population," stated Dr. Hashim Ahmed, Principal Investigator for the study, Division of Surgery and Interventional Sciences, University College London. "With the experience from this study, we believe we can further improve responses by optimizing dosing topsalysin based on the size of the tumor and not the prostate and optimizing the delivery of topsalysin, which we will confirm in a larger Phase 2 study."

Allison Hulme, Ph.D., chief operating officer and head of research and development at Sophiris, added: "The breakthrough for us is the ability to inject topsalysin, an enzymatically-activated ablative agent, directly into the identified tumor using 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 the favorable side effect profile observed to date, 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 associated with radical treatments that are aimed at the entire prostate."

The Phase 2a proof of concept study was a single-center, open-label study at University College London, which is well known for the focal treatment of prostate cancer in the UK. In this study, previously obtained multiparametric magnetic resonance images (mpMRIs) of each patient's prostate tumor lesions are mapped to real-time three-dimensional transrectal ultrasound using an elastic image-fusion software. These images are used to guide the injection of topsalysin to treat a single, histologically-proven, clinically significant prostate cancer lesion. The primary objective of the study was to evaluate the safety and tolerability, and the key efficacy variable was the change in the treated lesion on targeted biopsy after 6 months. The study was designed to assess whether topsalysin has the potential to provide patients with clinically significant, localized, low to intermediate risk prostate cancer a tissue-sparing cancer treatment that carries little in the way of side effects. A total of 18 patients were enrolled and treated in this study. Detailed results from this study will be presented at a future medical conference.

Webcast scheduled for today at 2:00 p.m. Pacific Time

The Sophiris management team will host a conference call and webcast today, June 9, at 2:00 p.m. Pacific Time to review the topsalysin prostate cancer data. Dr. Hashim Ahmed, University College London and Principal Investigator of the prostate cancer study will also participate in the call.

A live audio webcast will be accessible on the "Investor Relations" page of the Sophiris corporate website at www.SophirisBio.com. A replay will be available at the same location.

About Localized Prostate Cancer

Prostate cancer is the second most common form of cancer in men in the US with an estimated 220,800 new cases in 2015. Approximately 80 percent of patients in the US are diagnosed with localized disease. Research has shown that patients with early, localized disease have a low likelihood of the cancer spreading beyond the confines of the prostate; however, many men with clinically significant localized disease choose to undergo radical treatment. Radical therapies include surgery to remove the entire prostate and/or radiation. Potential toxicities from radical treatments can be significant and permanent and include erectile dysfunction, urinary incontinence, and rectal toxicity.

Topsalysin for the Targeted Treatment of Localized Prostate Cancer

Topsalysin (PRX302) has the potential to provide a focal targeted therapy for the ablation of localized prostate cancer while potentially avoiding many of the complications and side effects associated with whole gland radical treatments. The increasing use of multiparametric magnetic resonance imaging (mpMRI) and advances in mapping previously obtained mpMRI images with real-time three-dimensional ultrasound images enables physicians to more accurately locate tumors within the prostate when taking biopsies. This increases the accuracy with which men with clinically significant lesions are identified. It also enables the injection of an ablative agent, such as topsalysin, directly into previously identified clinically significant tumors located within the prostate.

Topsalysin, an inactivated pore-forming protein, was engineered to be activated only by enzymatically-active PSA, which is present only in prostate tissue. The targeted focal treatment of prostate cancer is in line with current treatments for solid tumors such as breast and liver, where the goal is to remove the tumor and preserve as much of the organ as possible.

About Sophiris

Sophiris Bio Inc. is a biopharmaceutical company developing topsalysin, a clinical-stage, targeted therapy for the treatment of urological diseases. Topsalysin has successfully completed a Phase 3 clinical study for the treatment of the symptoms of benign prostatic hyperplasia (BPH), and is designed to be as efficacious as pharmaceuticals, less invasive than the surgical interventions, and without the sexual side effects seen with existing treatments. Topsalysin has also successfully completed a Phase 2a study for the treatment of clinically significant, localized low to intermediate risk prostate cancer prior to radical therapy. For more information, please visit www.sophiris.com.

Certain statements included in this press release may be considered forward-looking, including expectations about the potential use of topsalysin for the ablation or focal treatment of prostate cancer tumors, expectations that the Company will able to use data from the proof of concept study to develop more effective delivery and dosing protocols for future clinical trials and implications that the Company will be able to continue to advance the development of topsalysin. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from those implied by such statements, and therefore these statements should not be read as guarantees of future performance or results. Some of the risks and uncertainties that could cause actual results, performance or achievements to differ include without limitation, risk associated with clinical trial development, including the risks that clinical data from a subset of patients may not be predicative of clinical data observed in subsequent patients or in subsequent clinical trials of the same drug candidate and other risks associated with the process of developing, manufacturing commercial scale drug products, obtaining regulatory approval of and commercializing treatments that are safe and effective, and risks relating to obtaining sufficient capital to enable the Company to continue to operate as a going concern and continue to advance clinical development of topsalysin. All forward-looking statements are based on Sophiris' current beliefs as well as assumptions made by and information currently available to Sophiris and relate to, among other things, anticipated financial performance, business prospects, strategies, regulatory developments, clinical trial results, market acceptance, ability to raise capital and future commitments. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by Sophiris in its public securities filings; actual events may differ materially from current expectations. Sophiris disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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