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Sophiris Bio Announces that the First Patient Has Been Dosed in Phase 2b Study of Topsalysin in Patients with Clinically Significant Localized Prostate Cancer

-Study includes option to re-treat with a second dose of topsalysin
-Study designed to confirm the dose and optimize delivery of topsalysin to guide Phase 3 plans

SAN DIEGO and VANCOUVER, British Columbia, June 8, 2017 /PRNewswire/ -- Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris") today announced that the first patient has been dosed in its Phase 2b study to evaluate the safety and tolerability of topsalysin in focally treating men with clinically significant localized prostate cancer. Topsalysin (PRX302) is an innovative, first-in-class pore-forming protein engineered to be activated only in the presence of enzymatically-active PSA, which is only found within the prostate.

This Phase 2b study will build on the successful Phase 2a proof-of-concept study for the treatment of localized prostate cancer which demonstrated that a targeted intraprostatic administration of topsalysin has the potential to safely ablate prostate tumor cells.

"Topsalysin has the potential to provide a much-needed opportunity to treat the patients who have clinically significant localized prostate cancer in a targeted focal manner, ablate pre-identified lesions and downgrade the patient to non-significant cancer," said Dr. Hashim Ahmed, professor and chair of urology, Imperial College London. "This would be extremely exciting and clinically meaningful for men, as it could help them either avoid or delay the need for radical therapies and significant side effects associated with radical therapy."

"We have the potential to provide an efficacious, less invasive treatment option for patients with clinically significant localized prostate cancer," said Randall E. Woods, president and CEO of Sophiris Bio. "Our goal with this international Phase 2b clinical study is to confirm the dose and optimize the delivery of topsalysin and to evaluate the safety and efficacy of a second dose of topsalysin in a clinical setting."

About the Phase 2b Study

The study is a multi-center, open-label, Phase 2b study evaluating the safety and efficacy of targeted intraprostatic administration of topsalysin for the treatment of histologically proven, clinically significant, localized prostate cancer. Approximately 40 patients will be enrolled in the study at multiple sites in the United States and the United Kingdom. The study will utilize previously obtained MRI images of each patient's prostate mapped to real time 3D ultrasound to target the delivery of topsalysin directly into and around a pre-identified clinically significant tumor. Safety and tolerability will be assessed post-treatment over 26 weeks. Efficacy will be assessed by biopsy and imaging (mpMRI) at 24 weeks. The

Company expects to receive six month biopsy data for all patients in the first quarter of 2018 assuming enrollment is completed as expected.

Importantly, the Phase 2b study includes an option to re-treat patients with a second dose of topsalysin, with a targeted biopsy to occur six months following the second dose. In order to be eligible for a second dose, the patient cannot have experienced a significant adverse event attributable to topsalysin or the dosing procedure from the first dose and the patient will need to have had a clinical response from the first dose but still have the presence of a clinically significant lesion area. The Company expects to have final biopsy data on all patients who receive a second dose in the fourth quarter of 2018.

About Localized Prostate Cancer

Prostate cancer is the second most common form of cancer in men in the US with an estimated 161,000 new cases in 2017. 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.

About Topsalysin

Topsalysin (PRX302), an innovative, "First-in-Class" pore-forming protein, was engineered to be activated only by enzymatically-active PSA, which is produced in large quantities exclusively within the prostate of men with prostate cancer. The targeted focal treatment of prostate cancer is in line with current treatment trends for solid tumors such as breast and liver, where the goal is to remove the tumor and preserve as much of the organ and organ function as possible.

Topsalysin 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 urologists 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.

About Sophiris

Sophiris Bio Inc. is a biopharmaceutical company developing topsalysin (PRX302) for the treatment of patients with urological diseases. Topsalysin is in Phase 2 clinical development for the focal treatment of localized prostate cancer as well as Phase 3 clinical development for the treatment of lower urinary tract symptoms of benign prostatic hyperplasia (BPH). Topsalysin is a highly potent ablative agent that is selective and targeted in that it is only activated by enzymatically active PSA which is found in high concentrations in the transition zone of the prostate and in and around prostate tumor cells. More than 400 patients have received treatment with topsalysin, which continues to appear to be safe and well tolerated. For more information, please visit www.sophirisbio.com.

Certain statements included in this press release may be considered forward-looking, including the quote of Sophiris' President and CEO, expectations about clinical trial results, including the timing of expected results and expectations about further 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, risks associated with clinical development, including the risk that enrollment will not be completed on the expected timeline, the results of the Phase 2b study will not be available when expected and risks that the results of the Phase 2b study will not replicate the results of the completed Phase 2a study of topsalysin for the treatment of localized low to intermediate risk prostate cancer or the study endpoint[s] will not be achieved, and other risks and uncertainties identified by Sophiris in its public securities filings with the SEC. 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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