Sophiris Bio Receives Positive Feedback from FDA Regarding Phase 3 Localized Prostate Cancer Clinical Trial Design

October 21, 2019

SAN DIEGO and VANCOUVER, British Columbia, Oct. 21, 2019 /PRNewswire/ -- Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), a biopharmaceutical company studying topsalysin (PRX302), a first-in-class, pore-forming protein, in late-stage clinical trials for the treatment of patients with urological diseases, today announced that following an End of Phase 2/ Pre-Phase 3 meeting with the United States Food and Drug Administration (FDA), there is agreement regarding the design of a single Phase 3 clinical trial to evaluate the potential of topsalysin as a targeted focal therapy to treat patients with intermediate risk localized prostate cancer.

The Phase 3 study design agreed upon with the FDA is consistent with the design previously agreed upon with the European Medicines Agency, as reported in June of this year. The study will enroll approximately 700 patients with a confirmed diagnosis of localized intermediate risk disease, to be equally randomized to receive a single administration of either topsalysin or placebo. The primary endpoint for the study will be the proportion of patients at 12 months who have failed treatment, defined as histological progression of disease, resulting in the need for alternative therapy, as assessed by an independent central adjudication panel. In addition, the FDA has indicated that in order to receive approval, Sophiris will evaluate all patients that progress to alternative treatments for an additional 12 months, for a total of 24 months of data, post the administration of study drug.

"The meeting with the FDA was positive, confirming the proposed Phase 3 study design is an acceptable approach to targeted focal therapy in the proposed patient population. The FDA's request to provide data on patients progressing to alternative therapy for an additional 12 months – for a total of 24 months – will, we believe, strengthen the overall data package for approval, providing valuable information on the durability of response following targeted focal therapy with topsalysin," said Professor Hashim Ahmed, Faculty of Medicine Department of Surgery & Cancer, Chair in Urology, Imperial College of London & Imperial College Healthcare NHS Trust and a member of the Scientific Advisory Board at Sophiris.

"The meeting with the FDA was productive and it was clear that if the proposed study were positive and the safety profile were to continue as observed in clinical trials to date, a single study has the potential to provide the clinical data to support regulatory approval in both the US and Europe," said Professor Scott Eggener, Faculty of Surgery and Radiobiology University of Chicago Medicine and a member of the Scientific Advisory Board at Sophiris.

"Now that there is a clear and agreed upon regulatory pathway forward for localized prostate cancer, we can now focus on our plan to fund this study and the Company going forward," said Randall E. Woods, our president and chief executive officer. "With the uncertainty of the regulatory pathway removed, we are advancing our discussions with multiple parties capable of funding the continued development of topsalysin."

About Localized Prostate Cancer

Prostate cancer is the second most common form of cancer in men in the United States with an estimated 175,000 new cases in 2019. Approximately 77 percent of patients in the United States 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" transmembrane pore-forming protein, was genetically modified to be activated only by
enzymatically-active PSA, which is produced in large quantities 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 targeted focal therapy for the ablation of localized prostate cancer lesions 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 software to co-register 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 late-stage clinical biopharmaceutical company developing topsalysin (PRX302) for the treatment of patients with urological diseases. Topsalysin has completed two Phase 2 clinical trials for the focal treatment of localized prostate cancer and has completed one Phase 3 study of topsalysin for the treatment of the 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. Our continuing development of topsalysin is depending on obtaining additional financing and/or entering into partnering or other strategic transactions. There is no assurance that we will be able to enter into partnering or other strategic transactions or obtain additional financing. For more information, please visit www.sophirisbio.com.

Certain statements included in this press release may be considered forward-looking, including the expectations about further development of topsalysin (PRX302), plans relating to execution of a Phase 3 clinical trial in localized prostate cancer, Sophiris' liquidity or capital requirements and the ability to obtain additional financing or execute other strategic alternatives. 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, risks that the Company will be able to fund future clinical trials or enter into a strategic transaction, risks about the Company's ability to continue as a going concern and other risks and uncertainties identified by Sophiris in its public securities filings with the Securities and Exchange Commission. 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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