Sophiris Bio Receives Positive Feedback from European Medicines Agency Regarding Phase 3 Localized Prostate Cancer Clinical Trial Design

June 19, 2019

Conference call scheduled for today at 9:30 a.m. EDT

SAN DIEGO and VANCOUVER, British Columbia, June 19, 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 it has received formal scientific advice from the European Medicines Agency (EMA) regarding a proposed design of a Phase 3 clinical trial to evaluate the potential of topsalysin as a targeted focal therapy to treat patients with intermediate risk localized prostate cancer.

"Based on the safety profile of topsalysin in 451 patients in our clinical development program along with the efficacy seen in our Phase 2 studies in localized prostate cancer, we approached the EMA with our proposed study design for a single Phase 3 trial to support registration in Europe, and we are pleased to have now obtained formal feedback from the Agency," said Randall Woods, president and CEO of Sophiris. "We believe that data from a single Phase 3 trial, if successful, will be sufficient to support market approval in Europe."

The Phase 3 study design, agreed upon by the EMA, will enroll patients with a confirmed diagnosis of intermediate risk disease. Approximately 700 men who meet the eligibility criteria will 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 intervention, per an independent central adjudication panel.

Webcast scheduled for today at 9:30 a.m. Eastern Time

The Sophiris management team will host a conference call and webcast today, June 19, at 9:30 a.m. Eastern Time to review the key details of the proposed Phase 3 clinical trial design and to address the potential commercial opportunity for topsalysin, along with 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.

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 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. For more information, please visit www.sophirisbio.com.

Certain statements included in this press release may be considered forward-looking, including the quote from the CEO and 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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