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Sophiris wows Street with prostate cancer data

By Michael Fitzhugh, Staff Writer

Sophiris Bio Inc.'s shares (NASDAQ:SPHS) rose 69.2 percent to a $1.98 close on Friday after publishing data showing that a single injection of PRX302 (topsalysin) durably destroyed localized prostate cancer tumor cells in half of the 18 men enrolled in an open-label phase IIa study.

Biopsy data at six months following treatment showed that two men experienced complete ablation of their targeted tumor. Seven patients saw a partial response, while nine men had no response.

Partial response was defined as either a reduction in the maximum cancer core length, the amount of cancer within a biopsy, or a reduction in Gleason pattern, a classification system frequently used to describe how aggressive a prostate cancer tumor is and how likely it is to spread. No serious adverse events or new safety signals were reported, the company said.

Topsalysin, an inactivated pore-forming protein, was engineered to be activated only by enzymatically active prostate-specific antigen (PSA), which is present only in prostate tissue. Sophiris licensed it from Johns Hopkins University and the University of Victoria.

"The results and learnings reported today give us confidence and support our plan to aggressively advance topsalysin into a phase II dose in [a] delivery confirmation study in localized prostate cancer, subject to securing an additional funding," said Randall Woods, president and CEO of Sophiris. The company engaged Oppenheimer & Co. Inc. in May to assist it in evaluating strategic alternatives to advance the program, including potential partnering arrangements, financings or strategic transactions.

A CLEARER PICTURE

Options for patients diagnosed with localized prostate cancer fall into two categories, said Sophiris' chief operating officer, Allison Hulme, during a conference call held to discuss the data. Patients can generally either commit to periodic PSA testing with biopsies as deemed necessary by their doctor or undergo radiation of their prostate or even complete surgical removal of the gland, she said.

"Advancements in imaging and the associated software technology create a novel opportunity for a highly potent ablative agent such topsalysin," said Hulme. "We can now inject topsalysin directly into and around a pre-identified clinically significant tumor. We can then use the same technology to visualize the tumor site after treatment to accurately biopsy and then measure the response to treatment."

But how much of the drug to inject and exactly how to best inject it are subjects that will require further work. On the dosage front, Hashim Ahmed, principal investigator for the study at University College London, said the dose-confirmation study is likely to proceed with individualized dosing based on the size of a patient's tumor rather than the size of his prostate. The development team also has "plans to optimize the delivery of topsalysin by attaching the injection needle to an infusion pump or potentially using a porous tip needle that we have identified," he said.

Regardless of the particulars of delivery, the ability to treat prostate cancer patients through infrequent visits to a doctor's office could end up attracting Sophiris fans from both the medical and payer communities. Both can find treatment goals frustrated when patients prescribed oral therapies either forget to take their pills or skip prescription refills.

Prostate cancer is the second most common form of cancer in men in the U.S. with an estimated 220,800 new cases in 2015, the company said. About 80 percent of patients in the U.S. are diagnosed with localized disease.

If approved in prostate cancer, topsalysin would compete not only with current treatment options for localized prostate cancer, but possibly other focal targeted therapies, including brachytherapy, cryotherapy, high-focused ultrasound, cyber knife, radio frequency ablation and laser ablation. In addition, in February, Nymox Pharmaceutical Corp., of Hasbrouck Heights, N.J., announced positive 18-month results with the intraprostatic administration of investigational therapy NX-1207 (fexapotide triflutate) in patients with low-grade localized prostate cancer. And, in January, Luxembourg-based Steba Biotecnology Ltd. submitted a marketing authorization application to the

EMA for the focal treatment of patients with low-risk localized prostate cancer, with vascular-targeted photodynamic therapy Tookad (padeliporfin di-potassium). (See *BioWorld Today*, Nov. 4, 2014.)

La Jolla, Calif.-based Sophiris is also developing topsalysin for the treatment of benign prostatic hyperplasia (BPH), which is more commonly known as enlarged prostate. In BPH, topsalysin also performed well, surprising many Sophiris-watchers by meeting its primary endpoint of statistically significant improvement of enlarged prostate symptoms over 12 months in final data released in November. (See *BioWorld Today*, Nov. 11, 2015.) //