OncoSec OMS ElectroChemotherapy for Head and Neck Cancer Shows Enhanced Quality of Life in Two Randomized Phase III Studies

Data Presented at the 8th International Conference on Head and Neck Cancer Demonstrate Equivalent Disease Control and Survival, and Improved Functional Outcomes and Quality of Life Compared to Surgery

SAN DIEGO, July 23, 2012 /PRNewswire/ -- OncoSec Medical Inc. (OTCBB:ONCS), a company developing the advanced-stage OncoSec Medical System (OMS) ElectroOncology therapies to treat solid tumors, announced data from an interim analysis of two randomized Phase III clinical trials, HNBE-01 and HNBE-02, using electrochemotherapy to treat locally recurrent and second primary squamous cell carcinoma of the head and neck (SCCHN). The data are being presented July 22-24 at the 8th International Conference on Head and Neck Cancer in Toronto, Canada. A link to the abstract can be found here: http://ahns.jnabstracts.com/Detail.aspx?ID=0778

In these studies, electrochemotherapy was compared against surgery for quality of life, safety, survival and local control at eight months, where local control is defined as destruction of the treated tumor without evidence of reappearance of the tumor at the treatment site. The data show OMS ElectroChemotherapy achieved the primary endpoint of preserving quality of life compared to surgery, and appears to be safe and comparable to surgery in achieving control in locally recurrent or second primary SCCHN. This therapy represents a viable alternative to potentially major surgical interventions for this patient population, where recurrent tumors in SCCHN usually have a poor prognosis with a local control rate of 40-50 percent and frequently associated loss of organ function.

Paul Goldfarb, M.D., Consulting Medical Director of OncoSec overseeing the Phase III studies, said, "Despite the early termination of this study, delayed interim analysis of these data clearly demonstrated there was equivalence in safety, local control at eight months and survival between electrochemotherapy and surgery, with a benefit of quality of life and function for patients who received electrochemotherapy."

OncoSec is evaluating the regulatory strategy alternatives for the most optimal path to market clearance based on the available Phase III and previously announced Phase IV data. Concurrently, the company is seeking partnering opportunities as it begins to approach the FDA and other regulatory bodies with product registration plans.
Punit Dhillon, President and CEO of OncoSec, said, "Interim analysis of these two Phase III studies, and the recently released data from the Phase IV study carried out in Europe, has demonstrated that the primary endpoint of maintaining quality of life was achieved. In addition, OMS ElectroChemotherapy appears to provide a potentially important treatment alternative to surgery that may address hard-to-treat tumors where there exists a particular need to preserve function and quality of life. These data strongly support our partnering efforts for the OMS ElectroChemotherapy program."

**Study Design**

HNBE-01 and HNBE-02 were designed as two open-label pivotal studies in which 214 patients with locally recurrent or second primary tumors, anterior and posterior to the tonsillar pillar, respectively, and amenable to surgical resection, were randomized 1:1 between surgery (control group) and electrochemotherapy (treatment group). The primary endpoint for these studies was quality of life, as measured by the Performance Status Scale for Head and Neck Cancer (PSSHN). Secondary endpoints were safety, local control at eight months and survival. For the treatment group, patients received local injection of bleomycin followed by electroporation. Radiation or neck dissection was permitted when warranted.

These studies were initiated in 2004 and subsequently closed in 2007, and were conducted at 22 sites in the United States, Canada, Eastern and Western Europe. Of the 214 enrolled subjects, 130 were randomized into HNBE-01 and 84 into HNBE-02. This study was terminated at the interim point following an independent data monitoring committee review; however, all treated patients were followed for up to two years to evaluate safety and efficacy. At the time of this analysis, there were a total of 98 evaluable subjects, 58 from HNBE-01 and 40 from HNBE-02.

**Efficacy and Quality of Life**

There were no statistically significant differences between time to death or local control rate at eight months between the control and experimental groups for HNBE-01 or HNBE-02 or the combination of both studies. Median time to death was statistically indistinguishable between surgery at 209 days versus 231 days for electrochemotherapy (p=0.55). Local tumor control at eight months was achieved in 92% of control group patients versus 90% of electrochemotherapy patients.

Quality of life was evaluated using the performance status scale for head and neck cancer patients (PSSHN), a functional outcome measurement assessing the ability to swallow, normalcy of diet and ability to eat in public. Assessment of quality of life by the PSSHN score showed a mean score of 269 at baseline versus 248 at eight months for the control group (p=0.036) versus 257 at baseline versus 249 at eight months for the electrochemotherapy group (p=0.59). While the scores in the electrochemotherapy group remained relatively unchanged at eight months, the surgery group in each trial showed a statistically significant decrease in overall function. The preservation of function and quality of life in the treatment group may be the result of the ability of OMS ElectroChemotherapy to spare surrounding vital tissue and reduce removal or destruction of additional tissue.
Safety

Early termination of these studies was recommended by the data monitoring committee following an interim review of safety data at the midway point of enrollment for HNBE-01 and HNBE-02. The interim analysis of long-term follow-up data at up to two years indicates there were no safety issues relating to electrochemotherapy, as reflected by the statistically significant equivalence between the groups in time to death. The most frequently reported adverse events, which were pain, nausea and local edema, were also equivalent for both groups of patients. There were no adverse experiences related to device performance observed among the 98 patients with squamous cell carcinoma of the head and neck who were evaluated, and no procedures were stopped as a result of device malfunction.

About OMS ElectroChemotherapy (Formerly SECTA)

On May 29, 2007 the Data Monitoring Committee (DMC) overseeing both the HNBE-01 and HNBE-02 studies recommended that enrollment of both studies be terminated, citing concerns regarding efficacy and safety, including mortality rates and enrollment futility. In the review by the DMC of interim data, the totality of the data indicated an unfavorable benefit to risk profile for the ElectroChemotherapy treatment arm relative to the surgery arm (control arm). As a result, the DMC suggested that the studies be stopped and no further subject enrollment be continued. Based on this recommendation, both studies were halted. The treated patients were followed up to two years to further evaluate safety and efficacy, as per protocol, but no additional data analysis was performed until recently by OncoSec.

Upon OncoSec's acquisition of these programs and other assets in 2011, OncoSec conducted a complete analysis of the data. This analysis indicated that there were no statistically significant differences between time to death or duration of local control between the control or ElectroChemotherapy experimental arms in either the HNBE-01 or HNBE-02 trials, or the combined groups across studies. Furthermore, none of the other parameters examined, including demographics, time since original diagnosis, prior therapies or tumor stage, showed any significant statistical difference between these parameters. The most frequent side effects were pain 35.4% for patients undergoing surgery and 46% for those treated with electrochemotherapy (all grades). Other items raised by the DMC were also evaluated and the Company is confident these can be, or have already been, addressed.

About OncoSec Medical Inc.

OncoSec Medical Incorporated is a biopharmaceutical company developing its advanced-stage OMS ElectroOncology therapies to treat solid tumor cancers and metastatic disease. OMS ElectroOncology therapies address an unmet medical need and represent a potential solution, for less invasive and less expensive therapies that are able to minimize detrimental effects resulting from currently available cancer treatments such as surgery, systemic chemotherapy or immunotherapy and other treatment alternatives. OncoSec's core technology is based upon its proprietary use of an electroporation platform, the OncoSec Medical System (OMS), to dramatically enhance the delivery and uptake of a locally delivered DNA-based immuno-cytokine
(OMS ElectroImmunotherapy) or chemotherapeutic agents (OMS ElectroChemotherapy). Treatment of various solid cancers using these powerful and targeted anti-cancer agents has demonstrated selective destruction of cancerous cells while sparing healthy normal tissues during early and late stage clinical trials. OncoSec’s clinical programs include three Phase II clinical trials for OMS ElectroImmunotherapy targeting lethal skin cancers. More information is available at www.oncosec.com. Additional information may also be found at OncoSec's Facebook, Twitter, and LinkedIn sites.

This press release contains forward looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered such "forward looking statements." Forward looking statements are based on management’s current preliminary expectations and are subject to risks and uncertainties which may cause our results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ from those predicted include our ability to raise additional funding, our ability to acquire, develop or commercialize new products, uncertainties inherent in pre-clinical studies and clinical trials, unexpected new data, safety and technical issues, competition and market conditions. These and additional risks and uncertainties are more fully described in OncoSec’s filings with the Securities and Exchange Commission. Undue reliance should not be placed on forward looking statements which speak only as of the date they are made. OncoSec disclaims any obligation to update any forward looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

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