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Celsion Corporation Reports Preclinical Results of ThermoDox® for the Treatment of Bladder Cancer Published in the International Journal of Hyperthermia

Higher Concentrations of Doxorubicin Accumulation and Distribution within the Bladder Wall Were Achieved with ThermoDox® Combined with Mild Local Hyperthermia Compared to Free Doxorubicin Alone

The Study Reinforces ThermoDox's Unique, Proprietary Mechanism of Action

LAWRENCEVILLE, N.J., April 13, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced publication of the article, "*Lyso-Thermosensitive Liposomal Doxorubicin for Treatment of Bladder Cancer*," in the International Journal of Hyperthermia. The article describes the results of porcine in vivo studies to evaluate ThermoDox® in combination with loco-regional mild hyperthermia for targeted drug delivery to the bladder wall as a potential treatment for bladder cancer. Swine bladder walls are similar in proportion and composition to human bladders. Doxorubicin accumulation and distribution within the bladder wall with ThermoDox® plus mild bladder hyperthermia was achieved at concentrations nearly ten times higher than with free intravenous doxorubicin combined with mild bladder hyperthermia. The study was conducted under a Cooperative Research and Development Agreement (CRADA) with the National Institutes of Health (NIH) to evaluate whether ThermoDox® combined with mild heating of the bladder can target drug delivery in the bladder.

It is estimated that over 79,000 new cases of urinary bladder cancer will be diagnosed in the United States in 2017 and over 16,800 people will die of the disease during this same period. Approximately 70 percent of new cases of bladder cancer present with non-muscle invasive disease and are typically treated by a technique called transurethral resection of the bladder which removes as much of the tumor as possible. However, 40 percent of patients with high risk non-muscle invasive disease experience a recurrence and another 33 percent experience disease progression. To reduce this high rate of recurrence, intravesical (in the bladder) therapy is used. Intravenous administration of free doxorubicin is commonly used as part of an effective standard perioperative chemotherapy regimen for muscle invasive disease; however results with intravesical doxorubicin have been less effective presumably from inability to deliver doxorubicin across the bladder urothelium (epithelial surface of the bladder).

The NIH studies were conducted under the direction of Dr. Bradford Wood, MD, Director, NIH Center for Interventional Oncology and Chief, NIH Clinical Center Interventional Radiology. The results of the studies are summarized below:

• Range of doxorubicin concentrations from the urothelium to the serosa (outer surface of the bladder):

- 20.32 - 3.52 ug/g for ThermoDox® + hyperthermia (HT)
- 2.34 - 0.61 ug/g for free doxorubicin + hyperthermia
- 2.18 - 0.51 ug/g for ThermoDox® with no hyperthermia

• Average doxorubicin concentrations in the urothelium/lamina:

- 9.7 +/- 0.67 ug/g for ThermoDox® + hyperthermia (HT)
- 1.2 +/- 0.39 ug/g for free doxorubicin + hyperthermia
- 1.15 +/- 0.38 ug/g for ThermoDox® with no hyperthermia

• Average doxorubicin concentrations in the muscularis:

- 4.09 +/- 0.81 ug/g for ThermoDox® + hyperthermia (HT)
- 0.86 +/- 0.24 ug/g for free doxorubicin + hyperthermia
- 0.62 +/- 0.15 ug/g for ThermoDox® with no hyperthermia

Computational model results were similar to the measured doxorubicin levels and suggest that adequate temperatures were reached within the bladder for drug release from the lyso-thermosensitive liposomal doxorubicin, ThermoDox®.

"The incomplete response of bladder tumors to intravesical drugs, like doxorubicin and mitomycin C, has been attributed in

part to inadequate drug delivery and poor penetration across the urothelium resulting in sub-therapeutic drug concentrations in the bladder wall," said Dr. Bradford Wood, MD, Director, NIH Center for Interventional Oncology and Chief, NIH Clinical Center Interventional Radiology. "To address this limitation, one promising strategy to enhance the permeability of the bladder wall to improve the efficacy of intravesical chemotherapy is the use of hyperthermia to stimulate the release of chemotherapeutic agents from thermosensitive nanocarriers for patients who have failed standard first line therapy for bladder cancer."

"The NIH's continued research interest in ThermoDox® and its application in the treatment of many difficult to treat cancers underscores the significance of ThermoDox's potential and its unique means of locally concentrating doxorubicin in a highly effective way," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "This study not only reinforces ThermoDox's mechanism, it provides further assurance that the conclusions from the NIH's independent analysis of ThermoDox® plus radio frequency ablation for the treatment of primary liver cancer are based on a broad set of clinical and preclinical evidence. The data presented by the NIH at the 2016 RSNA Annual Meeting in November 2016 showed that the longer the target tissue is heated, the greater is the clinical benefit. Multiple experiments conducted by Celsion suggest that this is the result of increased doxorubicin tissue concentration, and we believe provides strong validation for our ongoing global Phase III OPTIMA Study in primary liver cancer. A successful OPTIMA Study will provide the means to expand ThermoDox's utility for patients with bladder cancer."

About ThermoDox®

Celsion's most advanced program is a heat-mediated, tumor-targeting drug delivery technology that employs a novel heat-sensitive liposome engineered to address a broad range of difficult-to-treat cancers. The first application of this platform is ThermoDox®, a lyso-thermosensitive liposomal doxorubicin (LTLD), whose novel mechanism of action delivers high concentrations of doxorubicin to a region targeted with the application of localized heat at 40°C, just above body temperature. ThermoDox® has the potential to address a broad range of cancers.

Celsion's LTLD technology leverages two mechanisms of tumor biology to deliver higher concentrations of drug directly to the tumor site. In the first mechanism, rapidly growing tumors have leaky vasculature, which is permeable to liposomes and enables their accumulation within tumors. Leaky vasculature influences a number of factors within the tumor, including the access of therapeutic agents to tumor cells. Administered intravenously, ThermoDox® is engineered with a half-life to allow significant accumulation of liposomes at the tumor site as these liposomes recirculate in the blood stream. In the second mechanism, when an external heating device heats tumor tissue to a temperature of 40°C or greater, the heat-sensitive liposome rapidly changes structure and the liposomal membrane selectively dissolves, creating openings that can release a chemotherapeutic agent directly into the tumor and into the surrounding vasculature. Drug concentration increases as a function of the accumulation of liposomes at the tumor site, but only where the heat is present. This method damages only the tumor and the area related to tumor invasion, supporting more precise drug targeting.

About Celsion Corporation

Celsion is a fully-integrated oncology company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. The Company's lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer and in Phase II development for the treatment of recurrent chest wall breast cancer. The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies.

The Company has a Cooperative Research and Development Agreement (CRADA) with the NIH. Any reference to NIH should not be viewed as an endorsement or a recommendation of Celsion, its products or services. For more information on Celsion, visit our website: http://www.celsion.com. (LTSL/ThermoDox®, HEAT Study/HCC, OPTIMA Study/HCC)

Celsion wishes to inform readers that forward-looking statements in this release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; the uncertainties of and difficulties in analyzing interim clinical data, particularly in small subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission. Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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