Celsion Announces Publication of Findings from Single-Site Study in China of ThermoDox® Plus RFA in the Journal of Cancer Research and Therapeutics

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Data show overall survival improvement of 22.5 months with ThermoDox® plus RFA of 45 minutes or longer

Data provides additional corroboration of ThermoDox's potential for superior efficacy when combined with a well-executed RFA procedure

LAWRENCEVILLE, N.J, Aug. 27, 2019 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug-development company, announces that a study from a single site in China titled "Thermosensitive liposomal doxorubicin plus radiofrequency ablation increased tumor destruction and improved survival in patients with medium and large hepatocellular carcinoma: A randomized, double-blinded, dummy-controlled clinical trial in a single center" has been published in the *Journal of Cancer Research and Therapeutics.* These data were generated as part of the Phase III HEAT (Hepatocellular Carcinoma Study of RFA and ThermoDox®) Study sponsored by Celsion Corporation. The data from this single site at the Peking University Cancer Hospital and Institute in Beijing show an overall survival (OS) improvement of 22.5 months in patients with 3-7 cm unresectable hepatocellular carcinoma (HCC) tumors receiving combined radiofrequency ablation (RFA) and ThermoDox®, compared with the use of RFA alone.

In this study, patients received 50 mg/m^2 of ThermoDox® or placebo, plus RFA for 45 minutes or longer. Patients were followed for 11 to 80 months (average: 49.1 ± 24.8 months), with 18 of 22 patients completing the study. The mean OS for the ThermoDox® plus RFA group was 68.5 ± 7.2 months, which was significantly greater than the placebo plus RFA group (46.0 ± 10.6 months, pValue = 0.045). At the end of the follow-up period, the percentage of patients alive after 1, 3 and 5 years were as follows:

	ThermoDox + RFA	RFA Alone
% of patients alive at 1 year	90.0%	87.5%
% of patients alive at 3 years	90.0%	50.0%
% of patients alive at 5 years	77.1%	37.5%

The publication can be found in the *Journal of Cancer Research and Therapeutics* | Year: 2019 | Volume: 15 | Issue: 4 | Page 773 – 783. The authors are Yang W, Lee JC, Chen MH, Zhang ZY, Bai XM, Yin SS, et al. from the Departments of Ultrasound and Radiology, Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education), Peking University Cancer Hospital and Institute in Beijing. Professor Min-Hua Chen was a principal investigator in Celsion's Phase III HEAT Study, from which these data are derived, and is also a principal investigator in the Company's ongoing Phase III OPTIMA Study for the treatment of primary liver cancer with ThermoDox ® plus standardized RFA.

"Publication of Prof. Chen and colleagues' positive findings in this peer-reviewed journal provides further proof-of-principal that ThermoDox ®, in conjunction with 45 minutes or more of RFA, can have a significant positive impact on survival for certain patients with primary liver cancer," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Prof. Chen is a highly-respected thought leader in China, known for treating HCC with RFA, and the author of the definitive academic textbook instructing the use of RFA in liver cancer. Because China has the most cases of primary liver cancer in the world, accounting for fully half of the total, ThermoDox® holds particular importance there among health leaders."

"Although this was a study involving only one site as part of the Company's Phase III HEAT Study, Prof. Chen's results are compelling nonetheless, and support our prospective subgroup analysis of 285 patients that showed subjects receiving 45 minutes or more of RFA in combination with ThermoDox®, with a single lesion of 3-7 cm in size, had median overall survival of more than 7.5 years and an improvement over the control arm of more than 2 years. Moreover, these data, if duplicated in our Phase III OPTIMA Study, would result in a positive trial. We now eagerly await the results of the OPTIMA Study, with the first interim data analysis expected by the end of October, the design of which is based on this subgroup analysis from the HEAT Study," added Mr. Tardugno.

"The authors concluded that RFA with heat target delivery chemotherapy facilitated better tumor coagulation necrosis without additional toxicity. This combined treatment may improve the clinical efficacy of RFA or free doxorubicin and prolong survival in patients with medium to large HCC," said Nicholas Borys, M.D., Celsion's executive vice president and chief medical officer. "It is gratifying to see our investigators are reviewing their own data and finding results that are consistent with our overall findings. We believe this interest will continue to grow, helped in part by publication of studies such as this one and another on the HEAT Study that was published by the NIH earlier this month in the *Journal of Vascular and Interventional Radiology*, which showed that the duration of the heat source was important for the efficacy of our chemotherapeutic, ThermoDox®."

About ThermoDox®

Celsion's most advanced program is a heat-mediated drug delivery technology that employs a novel heat-sensitive liposome engineered to address a 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® is positioned for use with multiple heating technologies and has the potential to treat of a broad range of cancers including metastatic liver, recurrent chest wall breast cancer and non-muscle invading bladder 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 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 subject 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 development for other cancer indications. The Company's product pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies.

Forward-looking Statements

Forward-looking statements in this news 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 or regulatory authorities; and other risks detailed from time to time in the Celsion's periodic filings 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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