September 12, 2016

Celsion Corporation Announces Independent NIH Analysis Showing Treatment with ThermoDox® Plus RFA May Significantly Improve Overall Survival of Patients with Primary Liver Cancer

Conclusions Drawn from Results of Celsion's HEAT Study Prompted NIH Analysis;
Prior Subgroup Analysis of HEAT Study by Celsion Demonstrated a Two-Year Overall Survival Benefit Compared to Treatment with RFA Alone

Abstract Accepted for Oral Presentation at the 2016 RSNA Annual Meeting

LAWRENCEVILLE, N.J., Sept. 12, 2016 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced that the National Institutes of Health (NIH) has conducted an independent retrospective analysis of data from the intent-to-treat population of the Company's HEAT Study, a 701-patient study investigating ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin in combination with radiofrequency ablation (RFA) in primary liver cancer, also known as hepatocellular carcinoma (HCC). The findings of the NIH study will be presented during an oral session on Monday, November 28, 2016 at 1:50 pm CT during the 102nd Scientific Assembly and Annual Meeting of the Radiological Society of North America (RSNA) to be held on November 26 - December 2, 2016 in Chicago, IL. Celsion is currently studying the use of RFA as a heat source both for tumor ablation and to activate ThermoDox® as a means of treating the area surrounding the tumor, where untreated tumor may be present.

The NIH analysis, which sought to evaluate the correlation between RFA burn time per tumor volume (min/ml) and clinical outcome in patients treated with ThermoDox, concluded that increased burn time per tumor volume substantially improved survival in patients with solitary lesions treated with RFA + ThermoDox® compared to patients treated with RFA alone. These findings are consistent with Celsion's analysis of the HEAT Study data showing that in patients treated with RFA for more than 45 minutes, standardized RFA plus ThermoDox resulted in a statistically significant improvement in overall survival (OS) compared to standardized RFA alone.

"The NIH's independent analysis provides new confirmatory support indicating that the use of RFA for more than 45 minutes in patients treated with ThermoDox can have a correlative impact on reductions in tumor size and overall survival in patients with primary liver cancer," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We are encouraged that the NIH findings are consistent with Celsion's analysis of the HEAT Study data showing that in patients treated with RFA for more than 45 minutes, standardized RFA plus ThermoDox demonstrated a statistically significant improvement in overall survival compared to standardized RFA alone."

Mr. Tardugno added, "We also think it is noteworthy that Celsion's latest 285 patient subgroup OS readout from the HEAT Study reported that over a 3.5 year period, there was a consistent two-year survival benefit for patients with primary liver cancer - one of the most prevalent and most deadly types of cancer in the world - who were treated with ThermoDox plus optimized RFA over the optimized RFA-only group."

"We are pleased that the NIH findings will be presented to the scientific community at the 2016 RSNA Annual Meeting. We firmly believe that this event will advance the understanding of new and potentially curative approaches to the treatment of primary liver cancer, and that it will also provide strengthened validation for our ongoing global Phase III OPTIMA study, which is evaluating ThermoDox in combination with optimized RFA standardized to a minimum of 45 minutes versus standardized RFA alone in the treatment of primary liver cancer," Mr. Tardugno said.

Presentation Details

Abstract Number: 16013790

Title: RFA Plus Lyso Thermosensitive Liposomal Doxorubicin Improves Survival Using Metric of RFA Duration per Tumor Volume: Retrospective Analysis of Prospective Randomized Controlled Trial

Session: Interventional Oncology Series: Hepatocellular Carcinoma and Cholangiocarcinoma (VSI021)

Date and Time: Monday, November 28, 2016, 1:00 pm to 6:00 pm

About the OPTIMA Study

The Phase III OPTIMA Study is expected to enroll up to 550 patients in up to 75 clinical sites in the United States, Europe, China and Asia Pacific, and will evaluate ThermoDox® in combination with optimized RFA, which will be standardized to a minimum of 45 minutes across all investigators and clinical sites for treating lesions three to seven centimeters, versus standardized RFA alone. The primary endpoint for the trial is Overall Survival, which is supported by post-hoc analysis of data from the Company's 701 patient HEAT Study, where optimized RFA has demonstrated the potential to significantly improve survival when combined with ThermoDox®. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (iDMC).

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 anticancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. The Company has a Cooperative Research and Development Agreement (CRADA) with the NIH. Any reference to NIH should not be viewed as an endorsement 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 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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