November 29, 2016

Celsion Corporation Announces Presentation of Results from Independent NIH Analysis of ThermoDox® plus Optimized RFA for the Treatment of Primary Liver Cancer at the 2016 RSNA Annual Meeting

NIH Analysis of Data from Celsion's HEAT Study Reaffirms Correlation Between Increased RFA Burn Time per Tumor Volume and Significant Improvements in Overall Survival

Prior Subgroup Analysis of HEAT Study by Celsion Demonstrated a Two-Year Overall Survival Benefit for Patients Treated with ThermoDox® Plus Optimized RFA Compared with Optimized RFA Alone

LAWRENCEVILLE, N.J., Nov. 29, 2016 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced the presentation of results from an independent retrospective analysis conducted by the National Institutes of Health (NIH) on the intent-to-treat population of the Company's HEAT Study, a 701-patient study of 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 were presented during The Interventional Oncology Series: Hepatocellular Carcinoma and Cholangiocarcinoma at the 102nd Scientific Assembly and Annual Meeting of the Radiological Society of North America (RSNA) on Monday, November 28, 2016 from 1:00 pm to 6:00 pm CT and was moderated by Professor Riccardo Lencioni, lead European Investigator on Celsion's HEAT Study. Celsion is currently studying the use of RFA as a heat source both for tumor ablation and to activate ThermoDox® as a means of affecting the area surrounding the tumor, where later recurrence most often takes place.

The NIH analysis was conducted under the direction of Dr. Bradford Wood, MD, Director, NIH Center for Interventional Oncology and Chief, NIH Clinical Center Interventional Radiology. The NIH analysis, which sought to evaluate the correlation between RFA burn time per tumor volume (min/ml) and clinical outcome, concluded that increased burn time per tumor volume significantly improved overall survival (OS) in patients with solitary lesions treated with RFA + ThermoDox® compared to patients treated with RFA alone. More specifically, the analysis showed that a one unit increase in RFA duration per tumor volume improved OS by 20% in patients treated with optimized RFA + ThermoDox® compared to RFA alone.

This novel way of assessing the impact of the drug takes into account both the size of the tumor and the time of ablation, both of which appear to be important factors. The NIH analysis included 437 patients with a single lesion from the Company's HEAT Study, the same patient population being treated in the Company's ongoing Phase III OPTIMA Study. These findings are consistent with Celsion's own analysis of the HEAT Study data, which demonstrated that over a 3.5 year period, there was a statistically significant two (2) year survival benefit for patients treated with ThermoDox® plus optimized RFA over the optimized RFA only group.

"There is clear evidence that the duration of the RFA regimen used in combination with ThermoDox® is critical, as was demonstrated in the NIH's independent analysis," said Riccardo Lencioni, MD, FSIR, EBIR, Professor of Interventional Radiology, Vice Chair, Clinical and Translational Research, Department of Interventional Radiology, University of Miami School of Medicine. "Findings from this analysis provide additional confirmation that increased RFA burn time improves OS in patients administered ThermoDox®. For patients with intermediate HCC who are not optimal candidates for surgery, there exists a dire unmet need, and being able to offer these patients optimized RFA + ThermoDox® has the potential to be a meaningful paradigm shift in the current management of this deadly disease."

"It is an honor to have confirmatory support from the NIH 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 OS in patients with primary liver cancer," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "This analysis provides further validation for our ongoing global Phase III OPTIMA Study. In addition, learnings from a computational modeling study, an experimental animal study and the HEAT Study *post hoc* subgroup analysis, all of which are consistent with each other and which -- when examined together -- suggest a clearer understanding of a key ThermoDox heat-based mechanism of action: the longer the target tissue is heated, the greater the doxorubicin tissue concentration."

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 CT

The NIH presentation will be available on Celsion's website under "News & Investors - Scientific Presentations."

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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