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Celsion Announces Data Monitoring Committee Unanimously Recommends Continuation of Phase III OPTIMA Study of ThermoDox® for Primary Liver Cancer

LAWRENCEVILLE, N.J., Nov. 30, 2016 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced that following a review of data from its multinational, randomized pivotal Phase III clinical study of ThermoDox® in combination with optimized radiofrequency ablation (RFA) for primary liver cancer (the OPTIMA Study), the study's Data Monitoring Committee (DMC) has unanimously recommended that the trial continue enrollment. With approximately 40% of patients currently enrolled in the trial, Celsion expects to complete patient enrollment in this 550 patient trial by early 2018.

"Following the recent presentation by the NIH confirming our hypothesis that ThermoDox® in combination with optimized RFA can be a treatment with curative intent for HCC, we could not be more pleased that the DMC has recommended continuation of the OPTIMA Study without modification. Based on their review of all the available study data, the DMC has concluded that ThermoDox is safe for newly diagnosed, intermediate stage patients and that the study is being conducted according to the highest of clinical research standards," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We remain optimistic and encouraged by this decision, and by the potential that ThermoDox® has consistently demonstrated in patients with primary liver cancer, a patient population in dire need of new therapeutic options."

The DMC is comprised of an independent group of medical and scientific experts and is responsible for reviewing and evaluating patient safety and efficacy data for the Company's Phase III OPTIMA Study. The DMC reviews study data at regular intervals in order to ensure the safety of all patients enrolled in the trial and to monitor the quality and overall conduct of the trial including each site's compliance with the minimum RFA heating time of 45 minutes specified in the study protocol. The OPTIMA Study's design and statistical plan calls for two interim analyses by the DMC with the intent of evaluating its safety and efficacy to determine if there is overwhelming evidence of clinical benefit or a low probability of treatment success (a futility analysis) to continue, modify or terminate the trial.

On November 29, 2016, the Company announced results from an independent retrospective analysis conducted by the National Institutes of Health (NIH) on the intent-to-treat population of the 701 patient HEAT Study of ThermoDox® plus optimized RFA for the treatment of primary liver cancer. 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. 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 year survival benefit for patients treated with ThermoDox® plus optimized RFA over the optimized RFA only group.

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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