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Data Monitoring Committee Completes Mid-Study Review of Celsion's Phase III ThermoDox® OPTIMA Study in Primary Liver Cancer

OPTIMA Study at Over 60% Patient Enrollment, DMC Provides Unanimous Recommendation to Continue

Celsion Summarizes Regulatory Strategy for ThermoDox®

LAWRENCEVILLE, N.J., Aug. 07, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN), an oncology drug development company, today announced that the independent Data Monitoring Committee (DMC) for the Company's 550 patient, multinational, double-blind, placebo-controlled, pivotal Phase III clinical study of ThermoDox® in combination with radiofrequency ablation (RFA) for primary liver cancer (the OPTIMA study), has completed a planned interim analysis of the first 50% of patients randomized in the trial as of April 2017 for safety and efficacy and unanimously recommended that the study continue according to protocol to its final data readout based on the risk to benefit analysis by the Committee. The OPTIMA study to date has accumulated data within acceptable safety parameters.

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 Company also announced that enrollment in the OPTIMA Study is now over 60% of the 550 patients necessary to ensure that its primary end point, overall survival, can be achieved with statistical significance.

"Following independent confirmation of our hypothesis by the National Institutes of Health (NIH) in November 2016 that ThermoDox® in combination with optimized RFA can be a treatment with curative intent for primary liver cancer, we are very pleased that the DMC has recommended continuation of the OPTIMA Study without modification. Based on their review of all the available study data from 275 patients enrolled as of April 2017, 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 Nicholas Borys, MD, Celsion's senior vice president and chief medical officer. "A key component of the OPTIMA Study protocol is the investigators' adherence to the recommended RFA heating time for tumors greater than 3 cm. We are pleased to report that there has been a greater than 99% compliance rate with the study protocol."

On November 29, 2016, the Company announced results from an independent retrospective analysis conducted by the 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 RFA "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.

The NIH 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 survival benefit of approximately 2 years for patients treated with ThermoDox® plus optimized RFA over the optimized RFA only group.

"We are very pleased that the DMC has unanimously recommended continuation of the OPTIMA study based on their review of all available clinical data, both safety and efficacy, in over 275 patients," stated Mr. Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "The DMC's affirmative review is further evidence of ThermoDox's potential to provide a new and important first line therapeutic option for patients with primary liver cancer."

Regulatory Strategy for ThermoDox®. ThermoDox® has received FDA Fast Track Designation and in the prior HEAT Study had been designated as a Priority Trial for primary liver cancer by the National Institutes of Health. ThermoDox® has been granted orphan drug designation for primary liver cancer in both the U.S. and Europe. Based on prior discussions and subject to a successful trial, Celsion fully expects that the U.S. FDA and European EMA enrollment objectives will be met, and that the OPTIMA Study will also enrolled a sufficient number of patients to support registrational filings in China, South Korea, Taiwan and Vietnam, four other large and important markets for ThermoDox®.

In December 2016, the Company met with the China Food and Drug Administration (CFDA) to discuss the ongoing Phase III OPTIMA program and regulatory pathway for ThermoDox in China. During the meeting, Celsion presented the final overall survival data from the Chinese patient cohort from the prior HEAT study, which demonstrated a survival benefit in patients treated with ThermoDox plus optimized RFA versus optimized RFA alone. The CFDA informed Celsion that if the ongoing Phase III OPTIMA trial is successful, the trial could serve as the basis for a direct regulatory filing in China without the need to file for prior approval in the U.S. or European Union which is currently required for foreign company application. This would allow the Company to accelerate its plans for a regulatory filing in China and, if approved, provide for a significantly earlier launch date in China than originally expected.

The OPTIMA study's design and statistical plan incorporates two pre-planned interim efficacy analysis by the DMC (after patient enrollment is complete) with the intent of evaluating safety, efficacy and futility to determine if there is overwhelming evidence of clinical benefit or a low probability of treatment success to continue, modify or terminate the study. The results from the first interim efficacy analysis are expected to be made public following DMC review in Q1 of 2019.

About the OPTIMA Study

The Phase III OPTIMA Study is expected to enroll up to 550 patients in up to 70 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 optimized 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.

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. For more information on Celsion, visit our website: http://www.celsion.com. (CLSN-LTSL/ThermoDox® CLSN-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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