Data Monitoring Committee (DMC) Completes Planned Safety and Data Review of Celsion's Phase III OPTIMA Study of ThermoDox® for Treatment of Primary Liver Cancer

December 18, 2018

Current Combined, Blinded Progression-Free Survival (PFS) Rate for Both Treatment Arms Reaches 21.2 Months Compared to 19.8 Months for the Intent-To-Treat (ITT) Population in the HEAT Study Post-Hoc Analysis Subgroup

Current Combined, Blinded Overall Survival (OS) Rate for Both Treat Arms is Consistent with the ITT Population Observed in the HEAT Study Post-Hoc Analysis Subgroup

LAWRENCEVILLE, N.J., Dec. 18, 2018 (GLOBE NEWSWIRE) -- Celsion Corporation(NASDAQ: CLSN), an oncology drug development company, today announced that the independent Data Monitoring Committee (DMC) for the Company's pivotal Phase III OPTIMA Study of ThermoDox® in combination with radiofrequency ablation (RFA) for treatment of primary liver cancer, has again unanimously recommended that the study continue according to protocol to its data readout. The DMC's evaluation and recommendation were based on the Committee's assessment of safety and data integrity for all 556 patients enrolled in the multinational, double-blind, placebo-controlled trial as of October 4, 2018.

"This DMC review is the first since enrollment completion in the OPTIMA Study and focused on patient safety and demographics," said Nicholas Borys, M.D., Celsion's senior vice president and chief medical officer. "We are pleased to see that event data such as PFS and OS is tracking very closely to what we saw in the HEAT Study subgroup. Furthermore, the OPTIMA patient demographics and risk factors are consistent with what we saw in our HEAT Study subgroup and our data quality metrics are meeting expectations. The collection of all data endpoints is meeting expectations. Finally, we are grateful for the excellent work being done at the sites by our investigators and the oversight that the OPTIMA DMC is providing."

This DMC review analyzed blinded data from the intent-to-treat population, consolidated for both arms, which showed that median PFS for the OPTIMA Study had reached 21.2 months as of October 4, 2018. These blinded, consolidated data continue to compare favorably to the HEAT Study median PFS of 13.8 months (all 701 patients) and 19.8 months (for the 285 patients in the subgroup of patients treated with RFA > 45 minutes) and remain consistent with our projections based on protocol enhancements informed by the HEAT Study results and the HEAT Study post-hoc analysis subgroup, the same patient population that the current Phase III pivotal study design was built on.

The DMC consists of an independent group of medical and scientific experts 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 study protocol. The OPTIMA Study's design and statistical plan incorporates two pre-planned interim efficacy analyses by the DMC 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.

"This DMC review represents another important step forward in the execution of our Phase III OPTIMA Study for ThermoDox®. The DMC concluded from their latest review that this pivotal clinical trial has been executed at a high-quality standard and in compliance with the study protocol including each site's compliance with the minimum RFA heating time of 45 minutes," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Other encouraging take-aways from this review was that we have only lost three patients to follow-up from the initiation of the trial in September 2014 and the blinded data from the intent-to-treat population, consolidated for both arms, showed that overall survival thus far is consistent with the HEAT Study subgroup on which the Study's statistical plan was based. The OPTIMA Study, like other oncology studies, is subject to tumor progression, and the timing of efficacy results is entirely event-driven. Based on the DMC's most recent observations, we now expect to reach the prespecified number of events for the first interim analysis during the third quarter of next year."

About the OPTIMA Study

The Phase III OPTIMA Study enrolled 556 patients in 60 clinical sites in the North America, 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 analyses 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. 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)

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ThermoDox is a registered trademark of Celsion Corporation.

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