September 27, 2017

Celsion Provides Update on ThermoDox® in the Phase III OPTIMA Study of Primary Liver Cancer

OPTIMA Study Enrollment is Approaching 70%

Independent Data Monitoring Committee Provided Unanimous Recommendation to Continue Study in August 2017

Investigators Meetings in Thailand and China Attended by 70% of Investigators in China and Asia-Pacific

LAWRENCEVILLE, N.J., Sept. 27, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN), an oncology drug development company, today provided a detailed update 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) which include recent investigators meetings in Bangkok, Thailand and Shanghai, China. With the growing incidence of primary liver cancer in China and Asia-Pacific, representing approximately 75% of the estimated 850,000 cases diagnosed annually, this region represents a strategically important element of the Company's global registration and commercialization strategy for ThermoDox®.

The Company announced that enrollment in the OPTIMA Study is now approaching 70% of the 550 patients necessary to ensure that its primary end point, overall survival, can be evaluated with statistical significance. The statistical plan for the OPTIMA Study calls for two interim efficacy analyses by the independent Data Monitoring Committee (DMC). The Company currently projects full patient enrollment by mid-2018 and the first pre-planned efficacy analysis after 118 overall survival events by the first quarter of 2019.

"With independent confirmation by the NIH of the relationship between RFA heating time and the significant impact that it has on overall survival when combined with ThermoDox®, OPTIMA Study investigators fully recognize the value of the findings from the HEAT Study, reinforcing their interest and support for our highly de-risked, ongoing global Phase III OPTIMA Study," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "The previously announced unanimous recommendation for study continuation by the independent Data Monitoring Committee was based on their review of all available clinical data from 275 patients, and is further evidence of ThermoDox's recognized potential to provide a new and important first line therapeutic option for patients with primary liver cancer."

The design of the OPTIMA Study is supported by a retrospective analysis of a large subgroup of 285 patients in the Company's previous 701 patient HEAT Study in primary liver cancer. This subgroup of patients who received ThermoDox® plus standardized RFA demonstrated a statistically significant improvement in survival of over two years compared to standardized RFA alone. The median overall survival in the ThermoDox® plus standardized RFA arm was approximately 80 months (6 ½ years), which is considered a curative treatment for primary liver cancer.

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 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 consistent with the HEAT Study in patients treated with ThermoDox® plus optimized RFA over the optimized RFA only group.

In August 2017, the Company's Data Monitoring Committee, comprised of an independent group of medical and scientific experts who are responsible for reviewing and evaluating patient safety and efficacy data, completed a planned interim analysis of the first 50% of patients randomized in the trial as of April 2017 and unanimously recommended that the OPTIMA Study continue as planned based on the risk to benefit analysis by the Committee. The OPTIMA Study to date has accumulated data within acceptable safety parameters.

"There is clear evidence that the duration of the RFA regimen is critical when treating patients with ThermoDox®, and the

totality of the data presented to date demonstrate that ThermoDox plus optimized RFA has a strong potential to serve as a curative therapy for patients with liver cancer," said Professor Won Young Tak, M.D., Ph.D., Division of Gastroenterology and Hepatology, Department of Internal Medicine, School of Medicine, Kyungpook National University, Daegu, Republic of Korea and lead investigator in South Korea for the Company's HEAT and OPTIMA studies. "The OPTIMA Study is designed to validate this approach in an indication where there exists a strong unmet need for effective treatment options."

Regulatory Strategy for ThermoDox®. ThermoDox® has received U.S. FDA Fast Track Designation and has been granted orphan drug designation for primary liver cancer in both the U.S. and Europe. Further, the U.S. FDA has provided ThermoDox® with a 505(b)(2) registration pathway. Subject to a successful trial, the OPTIMA Study has been designed to support registration in all key primary liver cancer markets. Celsion fully expects to submit registrational applications in the USA, Europe and China. The Company believes that applications will be accepted in South Korea, Taiwan and Vietnam, three other large and important markets for ThermoDox® subject to approval in Europe, China or the USA.

"The Company's optimism for Chinese registration is based on our multiple interactions with the China Food and Drug Administration," said Nicholas Borys, MD, Celsion's senior vice president and chief medical officer. "During our December 2016 meeting with the Deputy Director of the Center for Drug Evaluation, 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 China only cohort was found to be consistent with the overall HEAT Study findings. We were informed 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 the European Union. 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," noted Dr. Borys.

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)

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Source: Celsion Corporation