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

April 9, 2018

DMC Unanimously Recommends Continuation of OPTIMA Study Based on Safety Data From 411 Patients; Enrollment Now at 80%

Blinded Progression-Free Survival (PFS) Rate in the OPTIMA Study is Consistent With the Subgroup Patient Population That Showed Benefit in the HEAT Study

ThermoDox®-Highlighted Symposium, "Emerging Horizons in HCC: From Palliation to Cure," on April 12, 2018 at International Liver Congress

LAWRENCEVILLE, N.J., April 09, 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 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 unanimously recommended that the study continue according to protocol to its data readout. The DMC's recommendation was based on the Committee's assessment of safety and data integrity of the first 75% of patients randomized in the trial as of February 5, 2018.

"The DMC's latest recommendation to continue the ongoing OPTIMA Study further supports our confidence in ThermoDox® and the OPTIMA Study's design to demonstrate the safety and effectiveness of ThermoDox® plus standardized RFA therapy in the treatment of patients with primary liver cancer," said Nicholas Borys, M.D., Celsion's senior vice president and chief medical officer. "An important feature of the OPTIMA Study protocol is investigators' adherence to RFA heating time of greater than 45 minutes for tumors greater than three centimeters – a key determination from the in-depth analyses of our previously completed HEAT Study. Based on the DMC's review of the 411 patients enrolled in the OPTIMA Study as of February 5, 2018, it concluded that the integrity of the study is intact and that ThermoDox® is safe for continued enrollment of newly diagnosed, intermediate-stage patients. We note also that in the analysis of blinded data from the intent-to-treat population, consolidated for both arms, median progression free survival (PFS) was 20.8 months. This compares favorably to the HEAT Study median PFS of 13.8 months and is consistent with the hypothesis-generating estimates from the HEAT Study manuscript published in the October 2017 issue of the peer-reviewed medical journal, 'Clinical Cancer Research.'"

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 minimum RFA heating time of 45 minutes, which is specified in 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 analysis was the last planned interim analysis prior to enrollment completion in the OPTIMA Study, and it represents another important milestone in our ThermoDox® development program," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "With the recent addition of five new sites in China and Vietnam, we are rapidly approaching enrollment completion, which is currently at 80% of the 550-patient total necessary to statistically validate the Overall Survival primary endpoint. We expect to complete enrollment in the third quarter of 2018. Data from the first interim efficacy results from this important study may be available early in the second quarter of 2019."

Hepatocellular Carcinoma (HCC) Symposium at International Liver Congress 2018 on April 12, 2018

Celsion also announced today that it will be sponsoring a symposium titled, "Emerging Horizons in HCC: From Palliation to Cure," on April 12, 2018, at the International Liver Congress™ 2018, in Paris, France. The symposium will discuss the current treatment paradigm and new developments in treating intermediate-size HCC, including the role of tyrosine kinase inhibitors (TKIs) and immuno-oncology. The symposium will be led by co-chairs and HCC experts, Ghassan Abou-Alfa, M.D., a board-certified medical oncologist at Memorial Sloan Kettering Cancer Center in New York City, and Riccardo Lencioni, M.D., FSIR, EBIR, professor at the University of Pisa School of Medicine.

The slides from Prof. Lencioni's presentation, "Rethinking Our Approach to Intermediate-Size HCC," will be available on Celsion's corporate website at www.celsion.com following the symposium on April 12, 2018.

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 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 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 press 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; U.S. Food and Drug Administration 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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