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Celsion Announces Updated Overall Survival Data from HEAT Study of ThermoDox® in Primary Liver Cancer

Analysis of 285 Patient Subgroup Shows an Impressive Statistically Significant 59% Improvement in Overall Survival
Results at Two Years Post Treatment Continue to Support Protocol for Ongoing Phase III OPTIMA Trial

LAWRENCEVILLE, N.J., Feb. 23, 2015 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN) today announced updated results from its retrospective analysis of the Company's 701-patient HEAT Study of ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin in combination with radiofrequency ablation (RFA) in primary liver cancer, also known as hepatocellular carcinoma (HCC).Â Â As of January 15, 2015, the latest quarterly overall survival (OS) analysis demonstrated that in a large, well bounded, subgroup of patients (n=285, 41% of the study patients), the combination of ThermoDox® and optimized RFA provided a 59% improvement in OS compared to optimized RFA alone. The Hazard Ratio at this analysis is 0.628 (95% CI 0.420 - 0.939) with a p-value of 0.02.

"The consistency of the data from the HEAT Study over the past two years is quite compelling, demonstrating the significant potential for ThermoDox® in combination with an optimized RFA regimen to markedly improve overall survival in primary liver cancer patients," stated Riccardo Lencioni, MD, FSIR, EBIR, professor and director of the diagnostic imaging and intervention at the Pisa University School of Medicine in Italy.Â "These findings provide a strong rationale for the ongoing OPTIMA Study and may also underscore the interest of clinical investigators to evaluate the potential of ThermoDox plus optimized RFA for curative intent among intermediate stage HCC patients."

The data from the most recent quarterly HEAT Study post-hoc analysis continued to strongly suggest that ThermoDox® may significantly improve OS compared to a RFA control in patients whose lesions undergo optimized RFA treatment for 45 minutes or more.Â These findings apply to patients with single HCC lesions (64.4% of the HEAT Study population) from both size cohorts of the HEAT Study (3-5 cm and 5-7 cm) and represent a subgroup of 285 patients.Â

"Once again, our quarterly OS analysis of the HEAT Study data shows a meaningful, statistically significant survival benefit among patients treated with ThermoDox® plus optimized RFA versus optimized RFA alone, further underscoring our confidence in the protocol for our ongoing Phase 3 OPTIMA trial," stated Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "The lessons learned from the HEAT study together with prospective supportive preclinical study results formed the basis for our global Phase III OPTIMA Study evaluating ThermoDox® in combination with a standardized RFA protocol in primary liver cancer, and we look forward to sharing this latest data update with our investigators worldwide as we continue to advance this program."

The Phase III OPTIMA Study is expected to enroll up to 550 patients globally in up to 100 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 3 to 7 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).

"Investigators from 14 countries have demonstrated their confidence in ThermoDox plus optimized RFA," noted Nicholas Borys, MD, Celsion's senior vice president and chief medical officer.Â Â "The consistent and improving evidence of an overall survival benefit not only reinforces their interest, but also suggests that ThermoDox should be considered conditionally in patients presenting with unresectable, intermediate stage disease."

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.Â The

pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers.Ä Celsion has three platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™, TheraSilence™ and RAST ™.Â For more information on Celsion, visit our website: http://www.celsion.com.

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.Â 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 or the possible failure to make such acquisitions or licenses; 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.Â 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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