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

Latest Data Sweep from a 285 Patient Subgroup Shows An Impressive 57% Improvement in Overall Survival
Data Continues to Validate Phase III OPTIMA Study Design

LAWRENCEVILLE, N.J., July 28, 2014 /PRNewswire/ --Â 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 June 30, 2014, 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 57% improvement in OS compared to optimized RFA alone. Â The Hazard Ratio at this analysis is 0.639 (95% CI 0.419 - 0.974) with a p-value of 0.037.

"As the data from the HEAT Study matures, it increasingly underscores the significant potential of ThermoDox® plus optimized RFA 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 "There is a pressing need for new treatment options to address HCC, which is a highly prevalent and deadly cancer. The consistency and strength of the HEAT Study data over each of the last five quarterly data analyses provide a strong rationale and clear roadmap for further development of ThermoDox® in this indication."

As of June 30, 2014, data from the latest 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 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 For this group, clinical results indicate a 57% improvement in OS, a Hazard Ratio of 0.639 (95% CI 0.419 - 0.974), and a p-value of 0.037.

"The post-hoc HEAT Study data is striking in that it has consistently shown a marked OS benefit for ThermoDox® plus optimized RFA versus RFA alone in each of the quarterly data sweeps, with this 5th, and final data set demonstrating that this survival benefit is statistically significant," stated Michael Tardugno, Celsion's President and Chief Executive Officer. "This impressive clinical data set, together with prospective supportive preclinical study results and multivariate Cox Regression Analyses, reinforces our confidence in the protocol for our Phase III OPTIMA Study in primary liver cancer, which is evaluating ThermoDox® in combination with a standardized RFA protocol in primary liver cancer."

The HEAT Study and prior post-hoc analyses were presented at multiple medical conferences over the past year, including: the 2014 American Society of Clinical Oncology 50th Annual Meeting in June 2014; the 5th European Conference on Interventional Oncology in April 2014; the International Liver Cancer Association Annual Conference in September 2013; the European Conference on Interventional Oncology in June 2013; and the World Conference on Interventional Oncology in May 2013.Â Presentations were made by some of the most highly recognized liver cancer researchers and key HEAT Study investigators.Â Quarterly overall survival data analyses have been conducted with the full support of these researchers and clinical investigators.

The Company notes that, while the data and supporting analysis from the HEAT Study warrant additional clinical development, the information should be viewed with caution since it is based upon a retrospective analysis and this subgroup of the HEAT Study has not reached its median point for OS analysis.Â

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 EGEN-001, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers.Â Celsion has three platform technologies for the development of novel nucleic

acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™.Ä 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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