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Celsion Corporation Provides Clinical Update on ThermoDox® HEAT Study Findings

Updated Overall Survival in a Large Subgroup of Patients Provides a Basis for Continued Clinical Development

LAWRENCEVILLE, N.J., Oct. 24, 2013 /PRNewswire/ --Â Celsion Corporation (NASDAQ: CLSN) today announced that the latest overall survival data from its post-hoc analysis of results from the Phase III HEAT Study of ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin, supports continued clinical development through a prospective pivotal Phase III Study, subject to regulatory review and agreement. The data analysis was conducted with the support of the Company's key principal investigators, and its data and liver cancer experts.Â This post-hoc analysis followed the announcement on January 31, 2013, that ThermoDox® in combination with radiofrequency ablation (RFA) did not meet the Study's primary endpoint, progression-free survival (PFS).Â The Company continues to follow patients in the Study to the secondary endpoint, overall survival (OS).Â Data from three OS sweeps have been conducted since the top line PFS data was announced in January.Â Celsion expects to submit its proposed pivotal Phase III clinical protocol for FDA review in the fourth quarter of 2013 and anticipates initiating a multicenter global trial in the first half of 2014.Â Â

Emerging data from the HEAT Study post-hoc analysis has been presented at three scientific and medical conferences in 2013 (World Conference on Interventional Oncology in May 2013; European Conference on Interventional Oncology in June 2013 and International Liver Cancer Association Annual Conference in September 2013) by key HEAT Study investigators and leading liver cancer experts.Â The data from the HEAT Study post-hoc analysis suggests that ThermoDox® may markedly improve overall survival, when compared to the control group, in patients if their tumors undergo optimal RFA treatment.Â These findings apply to 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 (41% of the patients in the HEAT Study).Â Updated OS data from this subgroup of patients is summarized below:

- In the patient subgroup treated in the ThermoDox® arm whose RFA procedure lasted longer than 45 minutes (285 patients or 63% of single lesion patients) clinical results indicate an improvement in overall survival with a Hazard Ratio of 0.63 (95% CI 0.393 — 1.011) and a P-value = 0.056.Â The median in this subgroup has not been reached.
- In contrast, the patient subgroup treated with ThermoDox® whose RFA procedure lasted less than 45 minutes in duration (167 patients or 37% of single lesion patients) demonstrated a Hazard Ratio of 1.14 (95% CI 0.737 — 1.776) and a P-value = 0.547.Â The median in this subgroup has not been reached.
- The Hazard Ratios reported above, while more than sufficient to support additional clinical development, should be viewed with caution since they are not statistically significant and the HEAT Study has not reached its median for overall survival analysis.Â Celsion continues to follow all patients in the HEAT Study to the secondary endpoint, overall survival, and will update the subgroup analysis based on RFA heating duration.

"An important lesson learned from the HEAT Study is that RFA can be optimized in order to improve outcomes of patients with HCC.Â This is true for RFA alone and particularly true of RFA plus ThermoDox®.Â We have learned from the HEAT Study data and from computer simulations that RFA dwell time is a key factor for success.Â These data were confirmed in large animal studies which now give us the confidence to move forward with a pivotal study," stated Dr. Nicolas Borys, Celsion's Chief Medical Officer.Â "Further, we are encouraged that investigators from the HEAT Study have expressed a strong interest in participating in a follow-on clinical trial."

"Equally important is that the data supporting our continued development program has been carefully reviewed by our HEAT Study principal investigators, international liver cancer experts, former FDA reviewers and independent statisticians," noted Michael H. Tardugno, Celsion's President and CEO.Â "We will present these findings in detail to the U.S Food and Drug Administration during the fourth quarter and we will work with the Agency on the best path forward in a pivotal study."

About Celsion Corporation

Celsion is dedicated to the development and commercialization of innovative cancer drugs, including tumor-targeting treatments using focused heat energy in combination with heat-activated liposomal drug technology.Â Celsion has research, license or commercialization agreements with leading institutions, including the National Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, the UCLA Department of Medicine, the Kyungpook National University Hospital, the Beijing Cancer Hospital and the University of Oxford.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; HEAT Study data is subject to further verification and review by the HEAT Study Data Management Committee; the need for Celsion to evaluate its future development plans; termination of the Technology Development Contract or collaboration between Celsion and HISUN at any time; 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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