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Celsion Corporation Issues Statement Regarding Misleading Blog Entry

LAWRENCEVILLE, N.J., June 12, 2013 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN) today issued the following statement regarding a blog entry posted by Alpha Exposure, Contributor, on Seeking Alpha.com:

"Statements made in Alpha Exposure's blog entry are misleading and require clarification.Â Â

As is common in the biotechnology and pharmaceutical industry, Celsion has conducted a comprehensive post hoc analysis of the data from its Phase III HEAT Study of ThermoDox® in hepatocellular carcinoma (HCC) with its key principal investigators, data experts and liver cancer experts.Â This analysis followed the announcement on January 31, 2013, that ThermoDox® in combination with radiofrequency ablation (RFA) did not meet the Study's primary endpoint.Â Emerging findings from the HEAT Study post hoc analysis, which has provided important insights regarding the use of ThermoDox® in conjunction with RFA to treat HCC, suggests that ThermoDox® markedly improves progression-free survival (PFS) and overall survival (OS) in patients if their lesions undergo RFA for 45 minutes or more.Â These findings apply to HCC lesions from both size cohorts of the HEAT Study (3-5 cm and 5-7 cm) and represent a sizable subgroup of approximately 300 patients.Â In the patient subgroup treated in the ThermoDox arm whose RFA procedure lasted longer than 45 minutes (63% of single lesion patients), overall survival improved by 53% (Hazard Ratio of 0.65 and a $P_{\text{value}} = 0.105$) when compared to the control arm of RFA treatment only.Â While the Hazard Ratio reported above should be viewed with caution since the HEAT Study has not reached its median point for overall survival analysis, there is a strong signal which our investigators and data experts consider to be encouraging and sufficient to warrant additional clinical investigation.Â These data were presented at a recent medical meeting of interventional oncology by two of Celsion's lead investigators.Â Furthermore, the detailed data has been submitted for peer review at upcoming international meetings in liver oncology and interventional oncology.Â HEAT Study investigators have agreed to the submission of the HEAT Study results and the post hoc data for peer review.Â

Celsion is refining the appropriate theoretical models to establish quantitative predictions for the influence of RFA heating time on local tissue concentrations of ThermoDox®.Â Empirical studies will then be used to verify the model predictions using appropriate animal studies which are targeted for completion over the summer.Â Assuming that our hypothesis is supported by non-clinical studies as well as continued follow-up of patients in the HEAT Study to the overall survival endpoint, we will meet with the U.S. Food and Drug Administration to discuss these findings.Â We would plan to propose a regulatory path forward which may include additional clinical studies based on FDA's predictive enrichment guidance.Â Furthermore, investigators in the HEAT Study have expressed significant interest in participating in a follow-on clinical trial."

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 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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