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

Data Continue to Show a Statistically Significant Improvement in Overall Survival, Translating to a Greater Than Two-Year Survival Benefit Following Treatment with ThermoDox® Plus Optimized RFA

LAWRENCEVILLE, N.J., Aug. 6, 2015 /PRNewswire/ --Â Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, 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 As of July 15, 2015, the latest overall survival (OS) analysis demonstrated that in a large, well bounded, subgroup of patients (n=285, 41% of the HEAT Study patients), treatment with a combination of ThermoDox® and optimized RFA provided an average 58% improvement in OS compared to optimized RFA alone. The Hazard Ratio (HR) at this analysis is 0.63 (95% CI 0.43 - 0.93) with a p-value of 0.0198.Â Median overall survival for the ThermoDox® group has been reached which translates into a 25.4 month (2.1 year) survival benefit over the optimized RFA group (79 months for the ThermoDox® plus optimized RFA group versus 53.6 months for the optimized RFA only group).

In the most recent post-hoc analysis of the HEAT Study, data continued to support and further strengthen ThermoDox®'s potential to significantly improve OS compared to an RFA control in patients with lesions that undergo optimized RFA treatment for 45 minutes or more.Â Findings from this analysis 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), representing a subgroup of 285 patients. Â Additional findings from this most recent analysis specific to the Chinese cohort of patients with single lesions (74% of the HEAT Study Chinese patient population) showed a 75% improvement (HR = 0.57 with a p-value of 0.08) in OS for the ThermoDox® plus optimized RFA group compared to optimized RFA only group.Â Patients in the Chinese cohort with single lesions between 3-5 cm showed a doubling of improvement (HR = 0.50 with a p-value of 0.06) in OS when treated with ThermoDox® plus optimized RFA.Â

"These results from the HEAT study reinforce the potential for ThermoDox® in combination with an optimized RFA regimen to serve as an effective treatment option that could significantly improve overall survival in primary liver cancer patients," statedÂ Dr. Nicholas Borys, Celsion's senior vice president and chief medical officer.Â "The data from our study suggests a greater than two year median survival advantage for the ThermoDox® plus optimized RFA group, a meaningful finding given that few treatments are effective in prolonging survival in HCC. We look forward to continued analyses from the maturing HEAT Study data in China and learning more about how this regimen can prolong survival in this deadly cancer.

"The continuing strength of the HEAT Study data reinforces our confidence in ThermoDox®Â as the first and only front line therapy for newly diagnosed HCC patients and further improves the risk profile of our Phase III OPTIMA Study, currently enrolling patients in 12 countries globally," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Equally important is the maturing data and the remarkable clinical benefit seen in the Chinese patient cohort.Â This large 221 patient subgroup represents a country with over 50% of the world's incidence (over 400,000 new cases) of HCC every year.Â These specific findings, along with the 25.4 months improvement in time to death seen in the global population, strengthen our options for discussions with the CFDA to identify a faster path to commercialization."

The Phase III OPTIMA Study is expected to enroll up to 550 patients in up to 75 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 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).

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 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.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™.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; 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.

Celsion Investor Contact

Jeffrey W. Church
Sr. Vice President and CFO
609-482-2455
jchurch@celsion.com

Celsion Media Contacts

Harriet ShelareÂ
Director, Communications
hshelare@celsion.com

Bill Berry
Berry & Company
212-253-8881
bberry@berrypr.com

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