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Celsion Presents Data on ThermoDox® plus Optimized RFA in Intermediate HCC at the 2nd Asian Conference on Tumor Ablation (ACTA)

LAWRENCEVILLE, N.J., Nov. 2, 2015 /PRNewswire/ --Â Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced the presentation of data from the Company's HEAT Study, highlighting the curative potential for ThermoDox® plus optimized radiofrequency ablation (RFA) in intermediate primary liver cancer, also known as hepatocellular carcinoma (HCC), as well as preclinical data on the correlation of heating duration during RFA in combination with ThermoDox. The clinical data were presented by two leading liver cancer experts from South Korea and Taiwan, Professor Won Young Tak, MD, Ph.D., Division of Gastroenterology and Hepatology, Department of Internal Medicine, School of Medicine, Kyungpook National University, Daegu, Republic of Korea and Dr. Shi-Ming Lin, MD, co-chair ACTA 2015 and vice chairman, Department of Gastroenterology and Hepatology, Chang Gung Memorial Hospital, Taipei, Taiwan, on October 30-31, 2015 at the 2015 Asian Conference on Tumor Ablation (ACTA) in Fukuoka, Japan.

"There is clear evidence that the duration of the RFA regimen is critical when treating patients with ThermoDox," said Professor Tak, lead investigator in South Korea for the Company's HEAT and OPTIMA studies. "Findings from the data presented at ACTA, including the multivariate analysis, HEAT Study data demonstrating compelling survival outcomes and supportive preclinical data, underscore the importance of Celsion's ongoing OPTIMA Study, which is designed to demonstrate the potential of ThermoDox with an optimized RFA regimen in this setting."

"The incidence rate of HCC within Asian countries is growing at an alarming rate, with current estimates projecting that Asia will account for approximately 75% of newly diagnosed cases annually," said Professor Lin, lead investigator in Taiwan for the Company's HEAT and OPTIMA studies. "The totality of the data presented demonstrate that ThermoDox plus optimized RFA has a strong potential to serve as a curative therapy for patients with liver cancer, where there exists a strong unmet need for effective treatment options."

The three presentations included:

- **"*Effect of Radiofrequency Ablation (RFA) Dwell Time (+/-) ThermoDox on Safety and Overall Survival (OS) Among 452 Intermediate Solitary HCC Patients With Lesions 3 to 7 cm: HEAT Study Data,*"** by Professor Won Young Tak, MD, Ph.D., Division of Gastroenterology and Hepatology, Department of Internal Medicine, School of Medicine, Kyungpook National University, Daegu, Republic of Korea and lead investigator in South Korea for the Company's HEAT and OPTIMA studies. Professor Tak discussed data from Celsion's latest HEAT Study post-hoc analysis, which suggests an overall survival benefit of over two years in the large subgroup of patients treated with ThermoDox plus optimized RFA (RFAÂ ≥ 45 minutes).
- ***"Effect of Standardizing Radiofrequency Ablation and Lyso-Thermosensitive Liposomal Doxorubicin (LTLD, ThermoDox®) on Overall Survival (OS) Among Patients with a Solitary 3 to 7 cm HCC Lesion: A HEAT Study Multivariate Analysis*,"** by Dr. Shi-Ming Lin, MD, co-chair ACTA 2015, vice-chairman, Department of Gastroenterology and Hepatology, Chang Gung Memorial Hospital, Taipei, Taiwan, and lead investigator in Taiwan for the Company's HEAT and OPTIMA studies. Dr. Lin reviewed the extensive data from Celsion's HEAT Study, including the results of multivariate analyses performed which clearly suggests that RFA heating or dwell time greater than 45 minutes was the only statistically significant variable that explained the significant improvement in overall survival (79 months in the optimized RFA plus ThermoDox® subgroup versus 53.6 months in the optimized RFA only subgroup) in a large, well bounded subgroup of 285 patients (41% of the HEAT Study patients).
- ***"Importance of Heating Time on the Local Drug Deposition During RFA in Combination with Lyso-Thermosensitive Liposomal Doxorubicin (LTLD) in a Porcine Model,"*** by Nicholas Borys, MD, Celsion's senior vice president and chief medical officer. Dr. Borys reviewed findings from a preclinical study demonstrating that in a porcine model, a direct correlation was observed between the duration of RFA heating, or dwell time, and the concentration of doxorubicin localized to the liver.

The presentation abstracts will be available on Celsion's website at http://investor.celsion.com/events.cfm.Â

About Celsion's Phase III OPTIMA Study

Celsion's Phase III OPTIMA Study is a global pivotal, double-blind, placebo-controlled study evaluating ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin, in combination with optimized radiofrequency ablation

(RFA) in HCC. The study is expected to enroll up to 550 patients in over 75 clinical sites in the North America, 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 for the OPTIMA Study 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 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.Â Celsion has two 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, including timing, enrollment and data; 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; 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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