

## Celsion Presents Data on ThermoDox® plus Optimized RFA in Intermediate Primary Liver Cancer at the 3rd Asian Conference on Tumor Ablation (ACTA)

## Supportive Data for the Phase III OPTIMA Study Demonstrates the Potential for a 2 Year Overall Survival Benefit

LAWRENCEVILLE, N.J., Oct. 31, 2016 (GLOBE NEWSWIRE) -- 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). The clinical data were presented by a leading liver cancer expert from South Korea, Professor Won Young Tak, M.D., Ph.D., Division of Gastroenterology and Hepatology, Department of Internal

Medicine, School of Medicine, Kyungpook National University, Daegu, Republic of Korea, on October 29, 2016 at the 3<sup>rd</sup> Asian Conference on Tumor Ablation (ACTA) in Seoul, Korea. Dr. Hyunchul Rhim from Samsung Medical Center in Soeul,

Korea, is the Chairman of the 3<sup>rd</sup> ACTA Conference and a principal investigator on the Company's OPTIMA Study.

Professor Tak's presentation, entitled **"Thermo-Sensitive Drug Assisted Ablation,"** highlighted 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 (RFA  $\geq$  45 minutes) as well as findings from preclinical studies demonstrating a direct correlation between the duration of RFA heating, or dwell time, and the concentration of doxorubicin localized to the liver.

"There is clear evidence that the duration of the RFA regimen is critical when treating patients with ThermoDox, and the totality of the data presented to date demonstrate that ThermoDox plus optimized RFA has a strong potential to serve as a curative therapy for patients with liver cancer," said Professor Tak, lead investigator in South Korea for the Company's HEAT and OPTIMA studies. "The OPTIMA trial is designed to validate this approach in an indication where there exists a strong unmet need for effective treatment options."

The Phase III OPTIMA study is a global pivotal, double-blind, placebo-controlled study evaluating 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.

"Our OPTIMA Study investigators continue to recognize the value of findings from the HEAT study, and their continued interest reinforces substantial and mounting support for and the de-risking of our ongoing global Phase III OPTIMA Study," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "The recent independent analysis conducted by the National Institutes of Health provides further confirmatory support indicating that the use of RFA for more than 45 minutes in patients treated with ThermoDox can have a correlative impact on reductions in tumor size and overall survival in patients with primary liver cancer."

Professor Tak's presentation will be available on Celsion's website under "News & Events - Scientific Presentations."

Celsion notes that NIH's analysis will be discussed in detail during an oral session on Monday, November 28, 2016 at 1:50 pm CT during the 102<sup>nd</sup> Scientific Assembly and Annual Meeting of the Radiological Society of North America (RSNA) to be held on November 26 - December 2, 2016 in Chicago, IL.

## About Celsion's Phase III OPTIMA Study

Celsion's Phase III OPTIMA Study is a global pivotal, double-blind, placebo-controlled study. 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. The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anticancer DNA or RNA therapies, including TheraPlas<sup>™</sup> and TheraSilence<sup>™</sup>. For more information on Celsion, visit our website: <a href="http://www.celsion.com">http://www.celsion.com</a>. (LTSL/ThermoDox®, HEAT Study/HCC, Optima Study/HCC)

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. 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; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission. 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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