International Liver Congress™ 2018 Symposium Highlights Celsion's ThermoDox® in Treatment of Primary Liver Cancer

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LAWRENCEVILLE, N.J., April 12, 2018 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced a presentation and discussion of ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin in Phase III development for the treatment of primary liver cancer, and the evolving treatment landscape for hepatocellular carcinoma (HCC), as part of a company-sponsored symposium at the International Liver Congress™ 2018, in Paris, France. The symposium titled, "Emerging Horizons in HCC: From Palliation to Cure," featured presentations by co-chairs and HCC experts, Ghassan Abou-Alfa, M.D., a board-certified medical oncologist at Memorial Sloan Kettering Cancer Center in New York City, and Riccardo Lencioni, M.D., FSIR, EBIR, professor at the University of Pisa School of Medicine.

Dr. Abou-Alfa's presentation, "New Developments in Targeted Therapies for HCC: The Mounting Wave of Immuno-Oncology," discussed recent developments in treating HCC, including the role of tyrosine kinase inhibitors (TKIs), immuno-oncology and CAR-T therapies, as well as advancements in chemotherapy and combination treatment with local therapy.

"HCC is a devastating disease with a poor prognosis, affecting an estimated 850,000 people globally," said Dr. Abou-Alfa. "Today, the five-year survival rate is less than 10%, and new, effective treatments that can change this statistic by meaningfully improving overall survival in patients with HCC are urgently needed. As a clinician, I am encouraged by recent innovations, from TKIs, advances in chemotherapy and immuno-oncology, to therapies like Celsion's ThermoDox®, which have potential to provide a true patient benefit in liver cancer, and I look forward to seeing survival outcomes from ongoing studies."

Prof. Lencioni's presentation, "Rethinking Our Approach to Intermediate-Size HCC" focused on the increasing incidence and burden of HCC globally, the limited overall survival benefit with current therapies at later stages of disease progression, and the potential for ThermoDox® to provide enhanced survival benefit with standardized radiofrequency ablation (RFA).

"ThermoDox® is the first treatment candidate for HCC designed for image-guided drug delivery to be tested in a large, multicenter Phase III trial," said Prof. Lencioni. "Post-hoc analyses of the first Phase III study of ThermoDox® – the HEAT Study – generated important findings that demonstrated its potential to meaningfully increase overall survival when target tissue is adequately heated with RFA for 45 minutes or longer. These analyses showed that ThermoDox® treatment with prolonged RFA heating can increase doxorubicin tissue concentration and could extend overall survival to more than two years. The company's ongoing second Phase III study, the OPTIMA Study, is designed to test this survival benefit hypothesis. If this hypothesis bears out in the OPTIMA Study, this would be very meaningful and highly encouraging as there are few available treatments effective in prolonging survival in HCC."

Celsion's Phase III OPTIMA Study is expected to enroll up to 550 patients in up to 70 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 optimized RFA alone.

"HCC is a disease characterized by high mortality and an increasing prevalence globally. Patients with primary liver cancer are underserved by current treatments, and Celsion is focused on raising awareness and advancing innovation in treating HCC," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Our Phase III OPTIMA Study for ThermoDox® continues to make steady progress, having now reached over 80% enrollment. We look forward to completing enrollment in the OPTIMA Study in the third quarter of 2018, with first interim efficacy results projected early next year."

The slides from Prof. Lencioni's presentation, "Rethinking Our Approach to Intermediate-Size HCC," are available on Celsion's corporate website at www.celsion.com.

About the OPTIMA Study

The Phase III OPTIMA Study is expected to enroll up to 550 patients in up to 70 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 optimized RFA alone. The primary endpoint for the trial is Overall Survival, which is supported by post-hoc analyses 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.

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 anti-cancer DNA or RNA therapies. For more information on Celsion, visit our website: http://www.celsion.com. (CLSN-LTSL/ThermoDox® CLSN-Optima

Study/HCC)

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ThermoDox is a registered trademark of Celsion Corporation.

Celsion Investor Contact

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

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