Principal Investigator Professor Riccardo Lencioni Presents Celsion ThermoDox® Trial Data at SPECTRUM 2020 Interventional Oncology Conference

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Company reaffirms its projection for second pre-planned interim efficacy analysis for Phase III OPTIMA Study in the second quarter of 2020

LAWRENCEVILLE, N.J., Feb. 04, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug-development company, announces that Prof. Riccardo Lencioni, M.D., FSIR, EBIR delivered a presentation titled "Thermally-Sensitive Ablation Enhancers: Where Do We Stand?" at the SPECTRUM 2020 Interventional Oncology Conference held in Miami , FLA last month. Dr. Lencioni is a professor in the Department of Radiology at the University of Pisa School of Medicine in Italy and is an Honorary Research Professor of Interventional Oncology at the Miami Cancer Institute. He was the lead principal investigator in Europe for the Company's completed Phase III HEAT Study in hepatocellular carcinoma (HCC), or primary liver cancer, using radiofrequency ablation (RFA) plus ThermoDox®, the Company's lead product.

The SPECTRUM Conference is the only interventional oncology conference endorsed by The American Society of Clinical Oncology (ASCO). In his talk, Prof. Lencioni focused on the HEAT Study subgroup analysis showing the duration of RFA heating time per tumor volume of 45 minutes or longer plus ThermoDox® was key to overall survival benefit in this patient population. He noted that in early-stage HCC, nearly 50% of patients with a solitary lesion of less than 5 cm on imaging have microsatellites on histology. While RFA and other energy sources are not able to treat these microsatellites, a thermosensitive drug carrier such as ThermoDox® would deposit increased amounts of doxorubicin in the margins of a tumor given increased ablation time.

"The significant attention ThermoDox ® is receiving among key opinion leaders at important medical conferences has helped build awareness of our drug in combination with RFA for treating HCC," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We are grateful to Prof. Lencioni for helping Celsion create the training video on RFA heating time for lesion sizes from 3 cm to 7 cm that is being used by all investigators in our current Phase III OPTIMA Study."

The Company's OPTIMA Study was based on the prospective analysis of the HEAT Study subgroup of patients who received 45 minutes or more of RFA energy. The OPTIMA Study was fully enrolled in August 2018 with 556 subjects from 65 clinical sites in 14 countries. At its first interim analysis in November 2019 following 128 patient events, or deaths, the independent Data Monitoring Committee (iDMC) unanimously recommended the OPTIMA Study continue according to protocol based on safety and data integrity.

The Company re-affirms its projection that its second pre-planned interim efficacy analysis will occur during the second quarter of 2020, following 158 patient events, or deaths. The hazard ratio for success at 158 events is 0.70, which is below the hazard ratio of 0.65 observed for the 285 patients in the HEAT Study subgroup of patients treated with RFA of 45 minutes or longer.

Mr. Tardugno added, "We were pleased that the HCC part of the SPECTRUM program featured invited faculty with ties to Celsion, such as Dr. Josep Llovet, Founder and Director of the Liver Cancer Program and Full Professor of Medicine at the Mount Sinai School of Medicine in New York, who is chair of the OPTIMA iDMC, and Dr. Ghassan Abou-Alfa of Memorial Sloan Kettering Cancer Center and Professor, Weill Medical College at Cornell University, both in New York City, who was a member of the HEAT Study DMC. The medical community's independent assessment, along with the National Institutes of Health's published confirmation of the hypothesis supporting the potential for ThermoDox as a curative treatment for the largest unmet need in oncology is gratifying indeed."

About SPECTRUM

The annual SPECTRUM conference offers attendees a comprehensive review of a variety of oncological diseases, combined with the latest developments in medical, interventional and surgical therapeutic options across multiple disciplines. A practical overview of how to incorporate emerging therapies into practice is presented through a multidisciplinary lens, intended to achieve the highest levels of success in the fight against cancer.

About ThermoDox®

Celsion's most advanced program is a heat-mediated drug delivery technology that employs a novel heat-sensitive liposome engineered to address a range of difficult-to-treat cancers. The first application of this platform is ThermoDox®, a lyso-thermosensitive liposomal doxorubicin (LTLD), whose novel mechanism of action delivers high concentrations of doxorubicin to a region targeted with the application of localized heat at 40°C, just above body temperature. ThermoDox® is positioned for use with multiple heating technologies and has the potential to treat a broad range of cancers including metastatic liver, recurrent chest wall breast cancer and non-muscle invading bladder cancers.

Celsion's LTLD technology leverages two mechanisms of tumor biology to deliver higher concentrations of drug directly to the tumor site. In the first mechanism, rapidly growing tumors have leaky vasculature, which is permeable to liposomes and enables their accumulation within tumors. Leaky vasculature influences a number of factors within the tumor, including the access of therapeutic agents to tumor cells. Administered intravenously, ThermoDox® is engineered with a half-life to allow significant accumulation of liposomes at the tumor site as these liposomes recirculate in the blood stream. In the second mechanism, when an external heating device heats tumor tissue to a temperature of 40°C or greater, the heat-sensitive liposome rapidly changes structure and the liposomal membrane selectively dissolves, creating openings that can release a chemotherapeutic agent directly into the tumor and the surrounding vasculature. Drug concentration increases as a function of the accumulation of liposomes at the tumor site, but only where the heat is present. This method damages only the tumor and the area subject to tumor invasion, supporting more precise drug

targeting.

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 development for other cancer indications. The Company's product pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies.

Forward-looking Statements

Forward-looking statements in this news 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 or regulatory authorities; and other risks detailed from time to time in the Celsion's periodic filings 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.

Celsion Investor Contact

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

Or

LHA Investor Relations
Kim Sutton Golodetz
212-838-3777
kgolodetz@lhai.com

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