Celsion Affirms July Timing for Second Interim Analysis of the Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer

June 25, 2020

LAWRENCEVILLE, N.J, June 25, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug-development company, today affirmed that the independent Data Monitoring Committee (iDMC) is scheduled to meet during the first half of July to conduct the second pre-planned interim safety and efficacy analysis of the Phase III OPTIMA Study with ThermoDox® plus RFA (radiofrequency ablation) in patients with hepatocellular carcinoma (HCC), or primary liver cancer. Members of the iDMC represent the global market for HCC and are based in the U.S., Canada and Europe, and Celsion believes that any logistical challenges to the Committee's performing its work presented by the global COVID-19 pandemic have been addressed. Celsion expects to announce the iDMC's recommendations and Company next steps soon after the meeting concludes.

Data lock for the second pre-specified interim analysis occurred during April 2020 after the prescribed minimum number of events of 158 patient deaths was reached.

As previously announced, the hazard ratio for success at 158 deaths is 0.70, which represents a 30% reduction in the risk of death compared with RFA alone. The p-Value required is 0.022. Both compare favorably with the hazard ratio of 0.65 and p-Value = 0.02 observed in the prospective HEAT Study subgroup upon which the OPTIMA Study is based.

Michael H. Tardugno, Celsion's chairman, president and chief executive officer, said, "The iDMC meeting is expected to take place as planned and we look forward to receiving their recommendation. While we are hopeful for a positive outcome, it is not a binary event for the OPTIMA Study. Should the data not reach the threshold for success, we believe the OPTIMA Study is ultimately well-positioned for success at the final analysis, if necessary. The final analysis would be based on 197 patient deaths where the hazard ratio for success is 0.75 or a 25% reduction in the risk of death, with a p-Value = 0.042. We believe that a successful study has blockbuster revenue potential and, more importantly, will be globally transformational for patients with HCC, the largest unmet need in oncology with more than 750,000 cases annually."

About the OPTIMA Study

The Phase III OPTIMA Study enrolled 556 patients at 65 clinical sites in North America, Europe, China and Asia Pacific. The Study is 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 3-7 cm in size, 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 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 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 of 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.

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