Celsion Reports Unanimous Independent Data Monitoring Committee Recommendation to Continue the Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer

November 4, 2019

- *The Data Monitoring Committee Signals that Patient Safety Data and Data Quality Meets Expectations and Company is to Proceed to Next Interim Analysis.*
- *The Pooled Progression-Free Survival (PFS) Data is Consistent with What Was Observed in the Pooled HEAT Study Subgroup Data. The Pooled HEAT Study Data Demonstrated a Median PFS of 16.8 months While the Latest Pooled OPTIMA Study Data Demonstrates Medium PFS of 17.3 months.*
- *The Median Follow-Up for Overall Survival is only 25 months at this Time Point which is Too Early for Estimates.*
- *A 2nd Pre-Planned Interim Efficacy Analysis is Projected for the 2nd Quarter of 2020 Following 158 Patient Deaths*

LAWRENCEVILLE, N.J. , Nov. 04, 2019 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced that the independent Data Monitoring Committee (iDMC) has unanimously recommended the OPTIMA Study continue according to protocol. The recommendation was based on a review of blinded safety and data integrity from 556 patients enrolled in the Company's multinational, double-blind, placebo-controlled pivotal Phase III study with ThermoDox® plus RFA (radiofrequency ablation) in patients with hepatocellular carcinoma (HCC), or primary liver cancer (the OPTIMA Study).

The iDMC pre-planned interim efficacy review followed 128 patient events, or deaths, which occurred in August 2019. Data presented demonstrated that PFS and OS data appear to be tracking with patient data observed at a similar point in the Company's subgroup of patients followed prospectively in the earlier Phase III HEAT Study, upon which the OPTIMA Study is based.

The data review demonstrated the following:

- The OPTIMA Study patient demographics and risk factors are consistent with what the Company observed in the HEAT Study subgroup with all data quality metrics meeting expectations.
- Median PFS for the OPTIMA Study reached 17.3 months as of August 2019. These blinded data compare favorably with 16.8 months median PFS for the 285 patients in the HEAT Study subgroup of patients treated with RFA > 45 minutes and followed prospectively for overall survival.
- At this time point, combined Overall Survival (OS) for both treatment arms is consistent with that observed in the 285 patient prospective HEAT Study subgroup.

- The OPTIMA Study has lost only 4 patients to follow-up from the initiation of the trial in September 2014 through August 2019; the trial design allows for 3% loss per year.

Michael H. Tardugno, Celsion's chairman, president and chief executive officer, said, "We are encouraged by the recommendation of the iDMC to continue the OPTIMA Study according to plan. While we have not unblinded the study to report a hazard ratio, PFS is tracking similarly to the subgroup of patients who received more than 45 minutes of RFA in our HEAT Study and were followed prospectively for more than three years. This subgroup in the HEAT Study demonstrated a 2-year overall survival advantage and a median time to death of more than 7 ½ years. We believe this tracking bodes well for success at our next pre-planned interim efficacy analysis, which is intended after a minimum of 158 patient deaths. We also note that the median follow-up for survival was only 25 months at time of data cut-off, which is too early for OS estimates, particularly when compared to the median follow-up for the HEAT Study subgroup which was 67 months. The OPTIMA Study, like other oncology studies, is subject to tumor progression, and the timing of efficacy results is entirely event driven. We estimate that our next interim safety and efficacy analysis will occur during the second quarter of 2020."

"The hazard ratio for success at 158 events is 0.70. This is below the hazard ratio of 0.65 observed for the 285 patients in the HEAT Study subgroup of patients treated with RFA > 45 minutes," Mr. Tardugno added.

The iDMC reviews study data at regular intervals, with the primary responsibilities of ensuring the safety of all patients enrolled in the study, the quality of the data collected and the continued scientific validity of the study design.

About the OPTIMA STUDY

The OPTIMA Study was fully enrolled in August 2018 with 556 subjects from 65 clinical sites in 14 countries. The design of the OPTIMA Study is based on the Company's HEAT Study, in which a subgroup analysis of 285 subjects received a single ThermoDox ® administration in combination with a 45 minute or longer RFA procedure in HCC patients with a single lesion of 3-7 cm in size. Followed prospectively for 3 years, those patients treated with ThermoDox® demonstrated a median survival of more than 7 ½ years and a survival benefit of more than 2 years over the control group. These data were published in the October 2017 issue of the peer-reviewed journal *Clinical Cancer Research*, and are available here.

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 higher, 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. The 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. For more information on Celsion, please visit 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. 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; 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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Source: Celsion CORP