Celsion Co-sponsors Hepatocellular Carcinoma Symposium at the International Liver Cancer Association (ILCA) Annual Conference

September 23, 2019

LAWRENCEVILLE, N.J., Sept. 23, 2019 (GLOBE NEWSWIRE) -- **Celsion Corporation** **(NASDAQ: CLSN)**, an oncology drug-development company, announces it co-sponsored a symposium focused on hepatocellular carcinoma (HCC) at the recent 13th Annual Conference of the International Liver Cancer Association (ILCA). Other sponsors included Bayer Healthcare Pharmaceuticals, Inc. and Exelixis, Inc., both of whom provide therapeutics for the treatment of advanced HCC. The program, titled "Master Class & Tumor Board: Composing Personalized HCC Treatment Strategies, Insights on Harmonizing Patient Care with a Multidisciplinary Ensemble," was held on September 20 in Chicago, and featured four speakers. The symposium's timing verges on the upcoming meeting of the Data Monitoring Committee's review of the first interim data for the Company's Phase III OPTIMA Study of its lead drug candidate, ThermoDox®, to treat HCC.

The program was chaired by Ghassan Abou-Alfa, MD, MBA, Memorial Sloan Kettering Cancer Center and Professor, Weill Medical College at Cornell University, both in New York City. The other participants were:

- Prof. Riccardo Lencioni, MD, FSIR, EBIR
  Department of Radiology, University of Pisa, Italy
  Hon. Res. Prof. Interventional Oncology
  Miami Cancer Institute, Miami

- Amit Singal, MD, MS
  Medical Director of Liver Tumor Program
  Associate Professor of Medicine
  UT Southwestern Medical Center, Dallas

- Robin K. (Katie) Kelley, MD
  Associate Professor of Clinical Medicine
  Helen Diller Family Comprehensive Cancer Center
  Division of Hematology/Oncology
  University of California, San Francisco

Dr. Abou-Alfa and Prof. Lencioni have been involved in the development of Celsion's lead product ThermoDox ® for the treatment of HCC, or primary liver cancer. A review of the data supporting Celsion's Phase III trial ThermoDox ® plus radiofrequency ablation (RFA) in newly diagnosed HCC patients, "The OPTIMA Study", was presented by Prof. Lencioni. He also noted that the Overall Survival study had accrued enough deaths to conduct the first pre-planned interim analysis. The prespecified analysis can provide the basis for a New Drug Application submission if a hazard ratio of 0.637 is achieved.

Michael H. Tardugno, Celsion's chairman, president and chief executive officer, said, "We were delighted to co-sponsor this informative symposium with leaders in the treatment of liver cancer. We fully believe that ThermoDox® holds potential to become the first and only first-line therapeutic treatment for HCC. By supporting this and similar CME symposia, our longer-term commercial strategy is to ensure that we secure support from key opinion leaders. ThermoDox® is currently in late-stage testing in our Phase III OPTIMA Study in conjunction with RFA, and we are pleased that Prof. Lencioni included ThermoDox® in his discussion titled 'The Next Wave: Expanding the Therapeutic Arsenal in Earlier-Stage Disease.' Symposia like these help to increase awareness of Celsion and our work in liver cancer among practitioners."

"ThermoDox ® is being studied as the first potential curative treatment for HCC in a large, randomized, multicenter Phase III trial," said Prof. Lencioni. "Post-hoc analyses of the Company's first Phase III study of ThermoDox ® – the HEAT Study – generated important findings that demonstrated its potential to significantly increase overall survival when target tissue is adequately heated with RFA for 45 minutes or longer. 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, ThermoDox® will be the first and only FDA approved drug for the treatment of HCC with curative intent."

OPTIMA Study Update

Separately, the Company reports that the date for the independent data monitoring committee (iDMC) meeting to review the findings of the first pre-planned interim efficacy analysis of its Phase III OPTIMA Study has been scheduled for late October. Celsion plans to announce the interim results and recommendations from the iDMC as soon as possible thereafter.

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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