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Celsion Announces Presentation Highlighting Phase III OPTIMA Study at the Asia-Pacific Primary Liver Cancer Expert Meeting

Liver Cancer Experts Endorse Pivotal Study Based On Convincing Clinical and Preclinical Data

LAWRENCEVILLE, N.J., July 11, 2016 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced that its ongoing Phase III OPTIMA trial evaluating ThermoDox® in primary liver cancer, also known as hepatocellular carcinoma or HCC, was featured during an oral presentation at the 7th Asia-Pacific Primary Liver Cancer Expert (APPLE) Meeting. ThermoDox® is the Company's proprietary heat-activated liposomal encapsulation of doxorubicin, for the treatment of HCC.

Soo-Young Park, M.D., Associate Professor, Kyungpook National University, School of Medicine Division of Gastroenterology and Hepatology, delivered the presentation, titled, "Radiofrequency Ablation +/- Lyso-Thermosensitive Liposomal Doxorubicin (LTLD) in Intermediate-Size Hepatocellular Carcinoma: The Ongoing Phase III OPTIMA Study." The OPTIMA Study is an ongoing global, pivotal, double-blind, placebo-controlled clinical trial evaluating ThermoDox® in combination with Radio Frequency Ablation (RFA) standardized to a minimum of 45 minutes across all investigators and sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The study was developed in consultation with leading primary liver cancer, statistical and regulatory experts, and is based on extensive analysis of prior clinical and preclinical studies of ThermoDox® plus standardized RFA.

"The OPTIMA study represents an important study in the field of HCC, one of the most common and deadly cancers worldwide," said Dr. Park. "ThermoDox® plus standardized RFA has the potential to significantly improve overall survival of newly diagnosed patients, and I look forward to working with my colleagues to further advance this trial."

"Data from the earlier HEAT Study suggest that not only does this approach potentially prolong survival, but may also serve as a curative treatment for HCC," stated Won Young Tak, M.D., Professor, Kyungpook National University, School of Medicine, Division of Gastroenterology and Hepatology. "If positive, this study could potentially establish ThermoDox® plus standardized RFA as a first-line treatment for HCC."

In July 2015, Celsion reported the latest overall survival (OS) analysis of the HEAT Study post hoc subgroup. The OS analysis demonstrated that in a large, well bounded, subgroup of patients (n=285 patients, 41% of the previous 701 patient HEAT Study), treatment with a combination of ThermoDox® and standardized RFA (defined as RFA standardized to a minimum of 45 minutes or sRFA > 45 min) provided an average 58% improvement in OS compared to standardized RFA alone. The Hazard Ratio (HR) at this analysis was 0.63 (95% CI 0.43 - 0.93), with a p-value of 0.0198. In this large subgroup, median OS for the ThermoDox® plus standardized RFA group translates into a 25.4 month (more than 2.1 year) survival benefit over the standardized RFA only group - totaling approximately 80 months (6-1/2 years, which is considered a curative treatment for HCC) for the ThermoDox® plus standardized RFA group versus 53.6 months for the standardized RFA only group.

"The strength of the preclinical and clinical data to date reinforces our confidence in the potential of ThermoDox in HCC and for a successful trial outcome," stated Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We are extremely encouraged with the investigators' interest and enthusiasm for our approach. With the trial enrolling patients in 13 countries, and in 9 of up to 20 sites in the Peoples Republic of China, we remain focused on the efficient execution of the only active Phase III study in newly diagnosed HCC patients."

The OPTIMA Study

OPTIMA, a pivotal, double-blind, placebo-controlled Phase III clinical trial, is expected to enroll up to 550 patients at up to 75 sites in the North America, Europe, China and Asia Pacific. As of June 2016, the study has been successfully enrolling patients at more than 50 clinical sites in 13 different countries in North America, Europe and Asia Pacific. In December 2015, Celsion announced that it had received a Clinical Trial Application (CTA) approval from the China Food and Drug Administration (CFDA) to conduct the OPTIMA Study at up to 20 additional clinical sites in China, the country where approximately 50% of the 850,000 new cases of primary liver cancer are diagnosed each year and where the Company aims to enroll more than 200 patients in the China territory, the minimum number required by the CFDA to file a New Drug Application (NDA), assuming positive clinical results.

The primary endpoint for the OPTIMA Study is overall survival (OS). The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (iDMC). The design of the OPTIMA Study is supported by the retrospective analysis of a large subgroup of 285 patients in the Company's previous 701 patient HEAT Study in primary liver cancer. The study is also designed to establish a clear path to approval in major liver cancer markets worldwide, with results from the OPTIMA Study, if successful, providing the basis for a global registration filing and marketing approval.

About LTLD (ThermoDox®)

Celsion's most advanced program is a heat-mediated, tumor-targeting 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. In one of its most advanced applications, LTLD, when combined with radiofrequency thermal ablation (RFA), has the potential to address a range of cancers. For example, RFA in combination with ThermoDox® has been shown to expand the "treatment zone" with a margin of highly concentrated chemotherapy when treating individual primary liver cancer lesions. The goal of this application is to significantly improve efficacy.

Celsion's LTLD technology leverages two mechanisms of tumor biology to deliver higher concentrations of drug directly to the tumor site. The first: 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, LTLD is engineered with a half-life to allow significant accumulation of liposomes at the tumor site as these liposomes recirculate in the blood stream. The second: When an external heating device heats the 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 release the chemotherapeutic agent directly into the tumor and into 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 related to tumor invasion, supporting 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 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 anticancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. For more information on Celsion, visit our website: http://www.celsion.com. (CLSN-TD CLSN-HS CLSN-OS)

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, 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, regulatory authorities; and other risks detailed from time to time in the 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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