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Celsion's Phase III ThermoDox(R) HEAT Study Recommended as Priority Clinical Trial for HCC

NCI Consensus Recommendation Published in Journal of Clinical Oncology

COLUMBIA, Md., Aug 03, 2010 /PRNewswire via COMTEX News Network/ -- Celsion Corporation (Nasdaq: CLSN) announced today that the consensus recommendations of the National Cancer Institute (NCI) Clinical Trials Planning Meeting (CTPM) for Hepatocellular Carcinoma have been released and published in the August 2010 issue of Journal of Clinical Oncology, the official publication of American Society of Clinical Oncology (ASCO). In addition to evaluating the current standard of care, the NCI panel also recommended Celsion's Phase III ThermoDox (R) HEAT Study as a Priority Clinical Trial for HCC.

"We are pleased this prominent panel of experts at the NCI Clinical Trials Planning Meeting have recognized the importance of our Phase III HEAT Study," stated Michael H. Tardugno, President and Chief Executive Officer of Celsion. "Upon completion of the trial and eventual marketing approval, ThermoDox plus RFA will provide an additional therapeutic option for patients afflicted with HCC, a dreadful disease with high unmet medical need." Dr. Nicholas Borys, Chief Medical Officer of Celsion Corporation commented, "This JCO article also reinforces the global importance of new therapies for HCC, and highlights the prominence of the ThermoDox program, which is now over 2/3rds enrolled in 75 global sites and 11 countries."

Celsion's global Phase III ThermoDox study for primary liver cancer plans to enroll 600 patients and is being conducted under a FDA Special Protocol Assessment (SPA). The study is designed to evaluate the efficacy of ThermoDox in combination with radiofrequency ablation (RFA) when compared to patients who receive RFA alone as the control. The primary endpoint for the study is progression-free survival. Additional information on the Phase III ThermoDox clinical study may be found at www.clinicaltrials.gov.

About ThermoDox*(R)*

ThermoDox*(R)* is a proprietary heat-activated liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers including breast cancer. ThermoDox*(R)* is administered intravenously and in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. Localized mild hyperthermia (39.5-42 degrees Celsius) releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

ThermoDox has already demonstrated remarkable evidence of clinical activity in Phase I studies for primary liver cancer and recurrent chest wall breast cancer. For the primary liver cancer indication, Celsion has been granted FDA Orphan Drug designation. For recurrent chest wall breast cancer, ThermoDox*(R)* is being evaluated in a pivotal Phase I/II open-label, dose-escalating trial that is designed to measure durable local complete response at the tumor site.

ThermoDox(R) is a registered trademark of Celsion Corporation

About ThermoDox Global Phase III HEAT Study

Celsion's global ThermoDox Phase III study for HCC, the most common form of primary liver cancer, is being conducted under a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA). The 600 patient study, is designed to evaluate the efficacy of ThermoDox in combination with RFA when compared to patients who receive RFA alone as the control. The primary endpoint is progression free survival with a secondary confirmatory endpoint of overall survival. A pre-planned, un-blinded interim efficacy analysis will be performed by an independent Data Management Committee when 50% of the progression-free survival endpoint events are realized in the study population. Based on an historical review of RFA cases, Celsion expects the study could be completed by the middle of 2011, and pending positive data, a New Drug Application would be submitted to the FDA before the end of 2011. Additional information on the ThermoDox Phase III clinical study may be found at http://www.clinicaltrials.gov.

About Primary Liver Cancer

Primary liver cancer is one of the most deadly forms of cancer and ranks as the fifth most common solid tumor cancer. The incidence of primary liver cancer is approximately 20,000 cases per year in the United States and is rapidly growing worldwide at approximately 1,000,000 cases per year, due to the high prevalence of Hepatitis B and C in developing countries. Among the standard treatment options for liver cancer is surgical resection of the tumor; however 70% to 80% of patients are ineligible for surgery. Radio frequency ablation (RFA) has increasingly become the standard of care for non-resectable liver tumors, but the treatment becomes less effective for larger tumors.

About Celsion

Celsion is dedicated to the development and commercialization of innovative oncology drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. Celsion has licensed ThermoDox(R) to Yakult-Honsha for the Japanese market and has a partnership agreement with Phillips Medical to jointly develop its heat activated liposomal technology in combination with high intensity focused ultrasound to treat difficult cancers. Celsion has research, license, or commercialization agreements with leading institutions such as the National Institutes of Health, Duke University Medical Center, University of Hong Kong, Cleveland Clinic, and the North Shore Long Island Jewish Health System.

For more information on Celsion, visit our website: 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 by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities and Exchange Commission.

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